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Efficacy and Cost-Effectiveness of the First Generation of HIV Prevention Interventions for People with Severe and Persistent Mental Illness

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Abstract

Background: People with serious mental illness are at elevated risk for human immunodeficiency virus (HIV) infection. A small body of published research has evaluated the efficacy of HIV prevention interventions that aim to help persons with mental illness modify sexual behaviors that place them at risk for HIV infection. Additional research has evaluated the economic efficiency (''cost-effectiveness'') of these interventions.
Aims of the Study: We provide a detailed and critical review of the efficacy and cost-effectiveness of randomized, controlled trials of HIV prevention interventions for this population. We present a brief overview of the epidemiology of HIV among men and women with serious mental illness and describe HIV risk factors for members of this population. The efficacy literature is critically reviewed, and the results of the available studies are compared using a common effect size metric. The cost-effectiveness of HIV prevention interventions for mentally ill adults is then reviewed.
Methods: The efficacy of interventions at reducing risk behaviors and increasing preventive behaviors was summarized using effect size estimation techniques. First, we reviewed interventions that have been evaluated in randomized clinical trials and published in the peer-reviewed scientific literature so as to summarize the interventions that have been subjected to the most rigorous evaluation. For each of the five studies that met the inclusion criteria, we briefly described the methodology and intervention content, summarized the evidence for intervention efficacy, and calculated appropriate effect size estimates. A narrative review of two cost-effectiveness studies published to date was included.
Results: The review of intervention efficacy indicated that the risk reduction interventions evaluated to date have had only limited success at helping people with severe mental illness reduce their HIV risk behavior. Most effect sizes indicating successful condom use increases were in the small or small to moderate range. Overall, studies with the largest sample sizes, and presumably the most generalizable results, produced smaller intervention effect sizes than studies with smaller samples. The cost-effectiveness literature revealed similarly mixed results: economic efficiency varied from not cost-effective to highly cost-effective.
Discussion: Limited information is presently available regarding the efficacy and cost-effectiveness of HIV prevention interventions for people with severe and persistent mental illness. Encouraging results were obtained in some, but not all studies. Methodological limitations will need to be addressed in the next generation of HIV risk reduction intervention studies for this population.
Implications for Health Care Provision and Use: Persons with severe mental illness warrant attention from health care providers due to elevated risk for HIV infection. Interventions discussed herein, focusing on information and behavioral skills training, can be employed until strategies with stronger results are developed.
Implications for Health Policies: Effective and cost-effective HIV risk reduction interventions are available for adults with mental illness and should be more widely implemented. The cost-effectiveness of these interventions could be further enhanced by screening potential participants for high-risk sexual behaviors.
Implications for Further Research: To advance the field, the next generation of intervention research for people with severe mental illness will need to improve upon the designs and intervention strategies of the first generation, include larger samples, and devote increased attention to the life circumstances and particular mental health issues of intervention participants.

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Introduction

People with serious mental illness are at elevated risk for human immunodeficiency virus (HIV) infection. According to a recent review, HIV seropositivity rates among people with mental illness in urban areas of the U.S. range from 3.1 to 22.9%,[1,2] in comparison with overall rates of 0.3 to 0.4% for the U.S. adult population.[3] Moreover, behavioral surveys indicate that 30 to 60% of people with mental illness are at risk of contracting HIV as a result of their sexual and drug

injecting risk behaviors.[4] As the 1997 NIMH Consensus Development Conference on Interventions to Prevent HIV Infection concluded,[5] there is an urgent need for the development and evaluation of prevention programs to help people with mental illness reduce their HIV risk.

Because funding for HIV prevention programs is limited, health departments, HIV prevention community planning groups, and other decision makers need accurate information about the cost-effectiveness of competing prevention programs to help them maximize the impact of public health spending. Therefore, in addition to assessing the behavior change efficacy of HIV prevention programs, it is also essential to evaluate the economic efficiency (or ''cost-effectiveness'') of these programs.

In this paper, we summarize and critically examine randomized HIV risk reduction intervention trials for adults with severe and persistent mental illness. In addition, we summarize and integrate the findings of cost-effectiveness studies that have been conducted on two of the randomized trials. The first section presents a brief overview of the epidemiology of HIV among men and women with serious mental illness and describes HIV risk factors for members of this population. The HIV prevention intervention efficacy literature is critically reviewed in the second section, and the results of each study are presented in a common effect size metric (see **Appendix**). The cost-effectiveness of these interventions is reviewed in the third section. The final section describes some of the weaknesses of the studies conducted to date, discusses unique challenges associated with conducting efficacy and cost-effectiveness analyses of HIV prevention interventions for this population, provides suggestions for future research, and discusses implications for health care and health policy.

HIV Seroprevalence and Risk Factors among Adults with Severe and Persistent Mental Illness

Most studies that have examined HIV seroprevalence in samples of people with severe and persistent mental illness have been conducted in the New York City area. For example, HIV seroprevalence rates between 5 and 8% have been reported for newly admitted psychiatric patients in New York.[6-8] Even greater seroprevalence (19.4%) has been documented among patients discharged from a homeless shelter psychiatric program[9] and among substance abusing patients admitted to psychiatric inpatient units in New York (22.9%).[10]

Fewer studies have examined the seroprevalence of HIV among people with mental illness outside of New York. One study found a 3% seroprevalence among inpatients at a psychiatric institution in Delaware.[11] Similarly, self-reported seroprevalence rates of 2 to 6% have been calculated for outpatients with severe mental illness residing in inner-city areas of Milwaukee, Wisconsin,[12-14] residents of an inpatient psychiatric clinic in Massachusetts,[15] and psychiatric patients attending clinics in Baltimore, Maryland.[16] Katz, Watts, and Santman found a 15% seropositivity rate among people with chronic mental illness living in an urban California community.[17]

Although the number of seroprevalence studies has decreased over recent years, one recent study has been particularly informative. Rosenberg and colleagues examined HIV, hepatitis B virus (HBV), and hepatitis C virus (HCV) seroprevalence among 931 men and women with severe and persistent mental illness receiving inpatient or outpatient care in Connecticut, Maryland, New Hampshire, and North Carolina.[2] They found that in large metropolitan areas in these states, the HIV seroprevalence was 5%, whereas in the small or non-metropolitan areas, the seroprevalence rate was 1.4%. These findings indicate that many of the estimates from New York City are indeed overestimates of the seroprevalence rate in other areas and should not be generalized. However, these rates of HIV infection, as well as the rates of HBV and HCV found in the Rosenberg et al. sample are still several times higher than rates expected in the general U.S. population.[2] Further, although participants with a history of injection drug use (IDU) and needle sharing had a higher seroprevalence than those with no IDU history, of those with no history of IDU, 1.4% had HIV suggesting a higher than expected rate of infection through sexual contact even in non-HIV epicenter areas.

The following characteristics have been found to be associated with heightened risk of HIV infection in people with severe and persistent mental illness. First, some characteristics of severe psychopathology increase HIV behavioral risk, such as difficulty in forming stable sexual and social relationships and in combating coercion as well as exploitation related to sexuality; and deficits in cognitive and problem-solving skills, assertiveness, impulse control, and adaptation skills.[12,18-21] Other correlates of serious mental illness that may place persons at particularly high risk for HIV infection are low perceived self-efficacy for safer sexual behaviors, such as correct condom use; perceptions that peers and sexual partners do not endorse safer sex norms; and poor sexual communication and assertiveness.[7,8,22-25]

Persons with mental illness often face numerous social and environmental cofactors and stressors that heighten HIV risk. These stressors include poverty and homelessness, deficient social support, limited access to health care systems, disorganized or chaotic life circumstances, and coexisting alcohol, crack cocaine, or other substance use.[4,26,27] Persons with severe mental illness are also more likely to reside in inner-city areas having high rates of infection with HIV and other sexually transmitted diseases (STDs), and may lead transient lifestyles, with living arrangements and social relationships constantly in flux.[28] The immediate challenges posed by life circumstances may understandably be viewed as more problematic by people with severe and persistent mental illness than the potential for HIV infection.[29]

The socioeconomic and psychological difficulties are associated with elevated levels of high-risk sexual and drug use behaviors, including having multiple, casual, or high-risk sexual partners.[17,30-32] Non-gay-identified men with serious mental illness may engage in unprotected sex with other men as well as with women.[10,12,33] Rates of condom use tend to be low, especially among younger individuals with mental

illness.[13,28,30] Finally, survival sex is common among economically disadvantaged persons with mental illness, who may exchange sex for money, food, drugs, or lodging,[14,28,29] which may lead to situations in which individuals, and especially women with severe and persistent mental illness, have little control over condom use.[26,34]

Review of HIV Prevention Efficacy

The first HIV prevention interventions for people with serious mental illness were short educational programs that typically provided general information on HIV and AIDS, risk factors for HIV transmission, and recommendations for reducing the risk of infection.[35-37] Many such programs used videotaped presentations, which in some cases were supplemented with opportunities for discussion and/or a question-and-answer period. Outcome variables were often limited to knowledge and attitudes rather than addressing changes in HIV risk behaviors. The focus of the present review is behavioral change, rather than knowledge, attitudes, or beliefs, because of the direct link between changes in certain sexual and drug-use behaviors and reductions in HIV transmission risk. This focus is not meant to imply that changes in HIV/AIDS knowledge, attitudes, and beliefs are not important intervention goals; in fact, changes in these constructs are seen as necessary, but insufficient by themselves, for risk behavior change.[38-39]

A handful of randomized, controlled trials evaluated the efficacy of HIV risk reduction interventions for people with serious mental illness for altering the sexual behaviors that place them at risk for acquiring or transmitting HIV (see **Table 1**). These interventions have taken two forms: (i) small-group interventions that emphasize behavioral skills (including correct condom use and sexual communication skills), knowledge, attitudes and motivation;[25,40-42] and (ii) a small-group intervention designed to teach individuals with severe mental illness skills to reduce their own behavioral risk and to encourage these individuals to advocate what they have learned to their peers.[33] The following objectives were common to both types of interventions: increasing participants' knowledge about HIV/AIDS; enhancing self-efficacy for condom use and sexual negotiation; strengthening positive intentions toward safer sex; increasing readiness for change; improving problem-solving skills; and reinforcing successful HIV risk reduction behavior changes.

The first published randomized trial of an HIV risk reduction intervention for persons with severe mental illness was conducted by Kalichman, Sikkema, Kelly, and Bulto.[40] These authors tested a four-session small-group intervention with individuals who were recruited, with no restrictions, through notices posted in waiting areas in mental health clinics and through referrals made by therapists (see **Table 1**). They were recruited from two psychiatric outpatient programs. Most participants (63%) were not married or lived with a partner, and 29% had at least one child. The mean years of education was 12.3; 63% had 12 years of education or less; 87% were unemployed; and 73% earned under $8,000 yearly. With respect to risk for HIV infection, 73% reported one or more sexual partners in the previous year; 13 % reported history of sexual transmitted diseases; 27% had been coerced into having sex; and 80% of men reported having homosexual experiences. One participant injected drugs, 13% reported having sexual partners who injected drugs, and 19% reported being monogamous in a relationship. Finally, regarding baseline HIV serostatus, 37% had been tested for HIV and were HIV negative.

The intervention included an emphasis on training in a range of specific behavioral skills (i.e., negotiation for safer sex, social problem solving, condom application, and drug needle cleaning) in addition to basic HIV/AIDS education and risk perception components. Participants in the intervention exhibited improved attitudes toward condoms and HIV-related knowledge, and increased intentions to use condoms the next time they had sex. The control group received the intervention after the intervention group completed their immediate follow-up assessment, so the authors collapsed groups and analyzed behavioral data as a pretest-posttest within-subject design. Analyses indicated that after the intervention, relative to baseline, participants had more conversations with sexual partners about safer sex and AIDS, engaged in fewer occasions of unprotected intercourse, engaged in more condom-protected intercourse, and increased their proportion of intercourse that was condom protected from 18% to 53%. Because follow-up data were not available for both groups, between group analyses were not conducted, and we were unable to calculate effect sizes from these data that would be equivalent to the other studies.

Kelly *et al* combined a small-group HIV risk reduction framework with safer sex advocacy training for men and women with mental illness.[33] Participants constituted of individuals with severe mental illness receiving mental health services at an inner city clinic. They were recruited by screening clinic patients for HIV risk. Eligibility criteria included individuals who were 18 years or older, who were sexually active outside of a long-term relationship, had multiple partners, had a partner who injected drugs, or had been treated for an STD in the previous year. Chart records indicated that more than 80% of patients had a history of past psychiatric hospitalizations, and many others had multiple hospitalizations. Participants who dropped out (N=46) did not differ in background and demographic characteristics from non-dropouts (N=104).

In this study, clients were randomly assigned to either (i) a single-session HIV education intervention (control); (ii) a seven-session prevention intervention based on social-cognitive theories of behavior change; or (iii) a seven-session intervention based on social-cognitive theory that included training on how to promote safer sex behavior to others through conversation. The third intervention condition combined the above skills training with three 90-minute sessions in which participants were encouraged to adopt the role of ''AIDS educators and advocates of behavioral change'' to acquaintances, friends, family members, and neighbors. The approach of the third condition was based on previous research with gay men. This research has identified, taught, and commissioned participants—who were recruited

Table 1. Characteristics of Randomized Controlled HIV Risk Reduction Interventions Conducted with People with Severe and Persistent Mental Illness.

Study	Participants	Intervention(s)	Outcome Variables, Assessment Schedule, Reporting Period	Results	Comments
Kelly *et al* (1996)	*N* = 104 *Age*: M = 33.7 years; SD = 6.4 *Gender*: 53% male *Ethnicity*: 52% Caucasian; 39% African American; 9% other *Primary Diagnosis*: 58% mood disorder; 20% schizophrenia; 11% anxiety disorder; 11% substance use or personality disorder *Location*: Milwaukee, WI *Screened for Risk Behavior*? Yes	Three groups: (1) 7-session (90 minutes each) small group cognitive-behavioral skills training plus advocacy (2) 7-session small group (90-minutes each) cognitive-behavioral skills training (3) one 60-minute AIDS risk reduction educational	Sexual partnerships (number of partners, % with multiple partners, number of new or casual partners, % with new or casual partners), exposure frequency (number of unprotected acts, percentage having unprotected sex, number of unprotected acts of vaginal or anal intercourse) Baseline, 3-month follow up	(1) (Advocacy group) improved significantly on all outcomes, and improvement was significant compared to the time-matched (2) on the unprotected sex variable. However, improvement in (1) was not significant compared to (3). (2) did not show significant improvement (or decrement) on any outcomes.	Unexpected finding that the 7-session cognitive-behavioral group plus advocacy training was more effective than the seven session cognitive-behavioral intervention but not the one session comparison condition.
Kalichman *et al* (1995)	*N* = 52 *Age* = 39.2; SD = 8 *Gender*: 52% male *Ethnicity*: 35% Caucasian; 19% African American; 8% other *Primary Diagnosis (non-exclusive)*: 42% chronic undifferentiated schizophrenia; 19% paranoid schizophrenia; 23% schizoaffective; 13% major affective disorder; 17% personality disorder *Location*: Milwaukee, WI *Screened for Risk Behavior*? Yes	Two groups: (1) control group who were wait-listed for the duration and later received the intervention (2) four 90-minute sessions with risk education, skills training, and self-management and problem solving training	Number of safe sex conversations with partner, frequency of unprotected intercourse, condom use (% occasions condom used) Baseline, 1- and 2- month follow up	At 1- and 2-month follow-up, intervention participants reported less frequent unprotected sex and more frequent safe sex discussions and condom use (within subject analysis). Aside from reduction in unprotected sex, these changes did not remain significant at the 2-month follow-up.	First randomized trial among people with severe and persistent mental illness. Unable to compare groups at a comparable follow-up assessment; therefore, between-group analysis was not presented.

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Study	Participants	Intervention(s)	Outcome Variables, Assessment Schedule, Reporting Period	Results	Comments
Otto-Salaj *et al* (2001)	*N* = 189 *Age* = 38.4; SD = 10.1 *Gender*: 46% male *Ethnicity*: 35% Caucasian; 51% African American; 6% Hispanic; 8% other *Primary Diagnosis*: 35% schizophrenia; 34% affective disorder; 18% schizoaffective disorder; 13% other *Location:* Milwaukee, WI *Screened for Risk Behavior*? Yes	Two groups: (1) 7-session small-group cognitive-behavioral skills training (2) 7-session time-matched comparison intervention focusing on relationships, stress, nutritional health, cancer and heart disease, and general sexual health	Frequency of protected, unprotected intercourse, % sexual intercourse occasions protected by condoms, number of sexual partners Baseline, 3-, 6-, 9-, and 12-month follow-up	Varied for men and women. Women significantly increased frequency of protected intercourse, risk reduction behavioral intentions and reduction in number of sexual partners in intervention condition (1) as opposed to control (2). Men in intervention condition (1) showed significant change in only HIV risk knowledge when compared to control (2).	Although most of the intervention effects diminished by the 12-month follow-up, the necessity for tailored prevention approaches was highlighted.
Susser *et al* (1998)	*N* = 59 *Age* = 35 *Gender*: 100% male *Ethnicity*: 58% African American; 35% Hispanic; 7% other *Primary Diagnosis:* 61% schizophrenia or schizoaffective disorder; 27% major depressive or bipolar disorder; 12% other *Location*: New York City, NY *Screened for Risk Behavior?* Yes (all were sexually active)	Two groups: (1) 15-session intensive cognitive-behavioral skills training (2) 2-session AIDS education program	Vaginal Episode Equivalent sexual risk index (assigns points based on each unprotected sexual episode) Baseline, 6- and 18-month follow-up	Both (1) and (2) participants improved sexual risk index score. (1) reported significant improvement in mean scores in comparison with (2).	Study limited because baseline equivalence for unprotected sex was not evaluated.

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Study	Participants	Intervention(s)	Outcome Variables, Assessment Schedule, Reporting Period	Results	Comments
Weinhardt *et al* (1998)	*N* = 20 *Age* = 36 *Gender*: 100% women *Ethnicity*: 65% Caucasian *Primary Diagnosis*: 50% schizophrenia; 30% bipolar; 20% major depressive disorder *Location*: Syracuse, NY *Screened for Risk Behavior*? Yes	Two groups: (1) 10-session, small group, sexual assertiveness skills-training, HIV/AIDS information, and HIV risk behavior feedback (2) wait-list control group	Behavioral intentions, HIV-risk behavior (frequency of unprotected intercourse), and HIV-preventive behavior (frequency of safe sex or HIV discussion with partner, frequency of condom use) Baseline, 2- and 4- month follow-up assessments	Reduction in unprotected intercourse not significant compared to control. Significant increase in condom use, sexual assertiveness, and HIV-related knowledge relative to control.	Sessions conducted over 2-week period to accelerate skills training. Small sample size of this pilot study limits confidence in conclusion. Intervention resulted in improvement in HIV-related knowledge and sexual assertiveness skills, but did not affect motivation for risk reduction.

Table 2. Effect Sizes for HIV Risk Reduction Interventions among People with Severe Mental Illness.

Study	Gender	*N*	Months to first follow-up	Outcome			
				Unprotected sex	Protected sex	Sex partners	Index (based on unprotected sex)
Kelly *et al* (1997)	Both	70[a]	3	0.13	0.21	0.21	–
	Both	62[b]	3	-0.06	-0.38	-0.54	–
Weinhardt *et al* (1998)	Female	20	2	0.74	1.02**	–	–
Susser *et al* (1998)	Male	59	6	–	–	–	0.74***
Otto Salaj *et al* (2001)	Female	83	3	0.02	0.52**	0.27	–
	Male	71	3	-0.03	-0.24	-0.20	–

Note: All effect sizes, with the exception of Susser *et al* (1998) are Cohen's *d*, computed on the mean (SD) paired change score from baseline to the first follow up assessment between the experimental and comparison groups. A dashed line indicates that data were not provided for that outcome. a = effect sizes based on 7-session advocacy group vs. one session educational comparison group, b = effect sizes based on 7-session cognitive-behavioral group vs. one-session comparison group. One-tailed significance levels based on hypothesis that experimental group would result in greater risk reduction than the control group in each study * $p < .05$; ** $p < .02$; *** $p < .01$.

for their popularity in their at-risk community—to disseminate messages in support of HIV risk reduction to family members and friends. The third intervention produced community-wide HIV risk behavior reductions.[13] It hinges upon attitude research in cognitive dissonance and belief information. This field has established that people who become advocates for a cause tend to adopt attitudes in line with their public advocacy.[43,44]

Members of the control group received an interactive, one-hour HIV/AIDS education session that provided general information on HIV/AIDS, HIV risk behavior, and strategies to prevent contracting and spreading the virus. In the second intervention condition, conducted in small, same-gender groups, participants attended seven 90-minute sessions led by trained facilitators. Intervention content included information on HIV/AIDS risk and misconceptions regarding HIV, instruction on personal risk and readiness for change, instruction and practice in the setting of personal HIV risk reduction goals, trigger self-management skill practice, condom use training and skills practice, negotiation skills training and practice, and role-play practice of condom use negotiation with sexual partners. For all three conditions, sexual risk behavior data were collected at baseline and at three-month follow-up. Whereas participants in the two seven-session intervention conditions both increased their self-efficacy for risk reduction, AIDS risk behavior knowledge, positive condom use outcome expectancies, and decreased their perceived barriers to condom use, only participants in the advocacy training condition significantly increased their use of condoms and reduced the number of partners with whom they had sex.

Between-group analysis comparing the advocacy group condition against the single session control group indicated that the advocacy group reported a greater reduction in the number of different sexual partners (effect size, $d = 0.21$), in the frequency of condom use ($d = 0.21$), and in the frequency of unprotected sex ($d = 0.13$). (The methodology utilized to calculate effect sizes is described in the **Appendix**.) Participants in the cognitive-behavioral group (without advocacy training) exhibited slightly less risk reduction than participants in the one-session comparison group (see **Table 2**).

Otto-Salaj and colleagues evaluated the effectiveness of an HIV risk reduction skills-building intervention with 189 adults suffering from serious mental illness attending five urban mental health clinics in Milwaukee.[41] Participants were recruited through letters sent out to clinic clients, brochures placed in waiting areas, and case managers' referrals. The main inclusion criteria were the following: 18 years of age or older, psychiatric diagnosis and hospitalization history indicative of severe mental illness, no psychosis during screening interview, and no developmental disability as primary diagnosis. Other criteria included: treatment for an STD in the previous year, drug injecting sexual partner, multiple sexual partners in the previous year, being a man who had sex with other men, or history of injecting drugs. Approximately 50% of individuals screened met entry criteria and were enrolled in the study.

Participants were randomly assigned to attend either a seven-session intervention in which they practiced skills directly related to HIV behavioral risk reduction, or seven sessions in which they practiced skills related to general health concerns, such as cancer, heart disease, and stress. The HIV risk reduction intervention was tailored by gender and emphasized such topics as realistically evaluating personal HIV behavioral risk; belief in one's ability to change HIV risk behaviors (i.e., behavior change self-efficacy); improving HIV risk reduction behavioral skills, such as trigger self-management and condom use skills, and sexual negotiation and communication skills; behavior change self-reinforcement; and change maintenance skills.

The effectiveness of this intervention differed for men and women. Men showed only significant change in HIV risk knowledge scores in response to the intervention, while women responded to the intervention with large changes in their attitudes toward condom use, risk reduction behavioral intentions, and sexual behavior between baseline and many of the intermediate follow-ups. The mean frequency of condom-protected intercourse during the previous 3 months increased from a mean of 0.38 occasions at baseline to 2.90, 2.76, and 2.83 occasions at 3-, 6-, and 9-month follow-ups respectively (the effect was not significant at the 12-month follow-up) for women in the intervention, and the increase was significant compared to the control condition. Moreover, there was a significant increase in the proportion of condom-protected sex acts, from 20.5% at baseline to 45.9% and 46.8% at the 9- and 12-month follow-up points. These results translate into the following effect sizes for between-group differences from baseline to the 3-month follow-up: frequency of unprotected sex, frequency of protected sex, and number of sex partners, among men, $d = -0.03, -0.24, -0.20$ respectively, and, among women, $d = 0.02, 0.52$, and 0.27 respectively.

Weinhardt, Carey, Carey, and Verdecias pilot-tested an intervention tailored for women with severe mental illness, recruited from a public outpatient facility with a two-group randomized design comparing the experimental intervention to a wait-list control condition.[25] The mean level of education was 11th grade, and they were unemployed on average. Eligibility for participation in the study consisted of a modified version of the 15-item HIV-Risk Behavior Screening Instrument.[28] The following behaviors were assessed in the HIV-Risk Behavior Screening Instrument: number of acts with and without condoms, number of acts with different partners (anonymous, non-monogamous, HIV-positive, or partners who injected drugs), alcohol use or other substances prior to intercourse, and trading sex for money, drugs, or a place to stay during the previous 2 months.

The 10-session small-group intervention focused on training participants in sexual assertiveness skills using intensive social skills training techniques, in addition to providing basic HIV/AIDS information as well as exercises designed to increase motivation for risk behavior reduction. Participants' risk behavior and psychological determinants of risk behavior were assessed at baseline and at two- and four-month follow-ups. Results indicated that, relative to controls, participants in the intervention increased their knowledge about HIV/AIDS and their sexual assertiveness skills as

evaluated with participants' responses in role-play scenarios. Condom use increased from baseline relative to the control group (d = 1.02), but frequency of unprotected intercourse did not decrease significantly (d = 0.74), although changes were in the hypothesized direction relative to the control group. A significant limitation to the interpretations of the results is the small sample size of the study (n = 9 in the intervention groups, and n = 11 in a wait-list control condition), and therefore the reliability and generalizability of the results must be viewed with caution.

Finally, Susser and colleagues evaluated a small-group HIV risk reduction intervention for men with serious mental illness recruited from a psychiatric program conducted in a New York City homeless shelter.[42] The men were enrolled into the clinical trial in groups of 10 to 20 in seven recruitment time frames. During the recruitment time frames, although 139 men attended an outreach program, 23 of them were too disturbed to give informed consent and so were ineligible. Out of 116 eligible men, 3 refused to participate and 16 men left the shelter prior to being assigned to an intervention group. In all, 83.6% of men (or 97 men) chose to participate in the study. The 97 participants included 59 sexually active men (having had anal, vaginal, or oral sex during the previous 6 months).

Participants were randomly assigned to receive either a 15-session intensive skills training intervention (n = 33) or a two-session AIDS education program (n = 26). The 15-session intervention addressed issues of special concern to homeless men, such as casual partners, non-exclusive relationships, sexual activity under the influence of drugs, and same sex partners, in addition to the more standard topics of correct condom use, risk trigger management, and other cognitive-behavioral risk reduction skills. The primary outcome variable was a sexual risk index, which the authors derived from occasions of unprotected anal sex (each worth 2 risk points), unprotected vaginal intercourse (1 risk point) and unprotected oral sex (0.1 risk points). At the 6-month follow-up, the mean risk index (SD) in the intervention group was 1.0 (2.0) and was 3.1 (3.6) in the control group. A limitation of the study as published is that although participants were equivalent on number of sex partners and types of partners at baseline, the groups were not evaluated for baseline equivalence on unprotected intercourse, which was the basis for the primary outcome variable. Thus, the effect size could not be computed based on change scores from baseline to the follow-up. Instead, the difference between the groups at follow-up was used as an effect size estimate, resulting in a large effect size of d = 0.74.

Review of HIV Prevention Cost-Effectiveness

To date, only two of the randomized, controlled trials of HIV prevention interventions for adults with mental illness – the small-group program studied by Otto-Salaj *et al* [41] and the interventions evaluated by Kelly *et al*[33]– have been subjected to rigorous cost-effectiveness analysis.[45,46] Although this is a very small sample from which to draw conclusions, these cost-effectiveness studies nevertheless are instructive.

These two analyses, both of which were conducted by authors of the present review, used a variant of cost-effectiveness analysis known as ''cost-utility analysis'' in which the main outcome is the net cost per quality-adjusted life year (QALY) saved by the intervention (a quantity known as the ''cost-utility ratio'').[47-49] The number of QALYs saved by an intervention is a measure of health outcome that takes into consideration not only any added length to the patients' lives, but also reductions in morbidity and improvements in quality of life.[50] The cost-utility ratio can be expressed as: (C – AT)/AQ, where C is the cost of implementing the intervention, A is the number of infections averted by the intervention, and T and Q, respectively, represent the savings in HIV/AIDS medical care and the number of QALYs saved for each prevented infection.[51] In the cost-effectiveness studies by Pinkerton *et al* [45] and Johnson-Masotti *et al*,[46] program costs were obtained through retrospective cost analyses and a mathematical model of HIV transmission was used to estimate the number of prevented infections, based on the sexual behaviors reported by intervention participants at the baseline and follow-up assessments.[51-53] These analyses used standardized, age-adjusted values for T and Q drawn from the literature.[54,55]

In the first cost-effectiveness study, Pinkerton and colleagues[45] evaluated the economic efficiency of the nine-session small-group intervention conducted by Otto-Salaj *et al* [41] using sexual behavior data collected at the baseline, 3- and 6-month follow-up assessments. (Data from the 9- and 12-month assessments were not included in the cost-effectiveness analysis because there were no statistically significant risk differences between the intervention and control groups at these time points.)

Because the mathematical model indicated that the intervention was minimally effective for male participants, averting few if any HIV infections, and hence not potentially cost-effective, Pinkerton *et al* restricted their analysis to female intervention participants.[45] The results of the modeling exercise indicated that the intervention had a relatively small effect, averting 0.028 HIV infections per 100 participants, and their sex partners, over a one-year period. Each averted infection was associated with a savings of 6.16 QALYs and $214,707 dollars in HIV/AIDS-related medical treatment costs.

The intervention cost approximately $679 per female participant (1999 dollars). The main costs were the monetary incentives given to participants and intervention staff salaries, which constituted 44 and 26% of the total intervention cost, respectively. The cost-utility ratio was $136,295 per QALY saved. Notably, the intervention study enrolled participants regardless of their sexual activity at baseline. Including participants who report no risk behavior at baseline reduces the mean observed risk reduction, hence the overall cost-effectiveness of the intervention. When the cost-effectiveness analysis was restricted to sexually active women, the cost-utility ratio fell to $71,367.

In the second study, Johnson-Masotti *et al* [46] evaluated the cost-utility of Kelly *et al*'[33] three prevention interventions–

single-session, seven-session cognitive-behavioral, and seven-session with advocacy training–for men and women with mental illness. The average cost of the single-session intervention was $178 per participant; the multi-session cognitive-behavioral and advocacy training interventions cost $629 and $786 per participant, respectively, in 1998 dollars. The major cost categories included incentives paid to participants, recruitment, screening, and training costs, rental fees for space to deliver the interventions, and material costs (flip charts, video tapes, anatomical models, condoms, pens). Combined, these cost categories accounted for 73, 71 and 69% of the total cost of the single-session, cognitive-behavioral, and advocacy training interventions, respectively.

In this analysis, each averted infection was associated with $207,077 (1998 dollars) in averted HIV-related medical care costs and a savings of 8.6 QALYs. For women, the single-session intervention averted 0.098 infections per 100 participants. The corresponding savings in medical care costs was $203 per participant, which exceeded the cost of the program. Therefore, this program was cost-saving–that is, the intervention would actually save money in the long run by preventing people from becoming infected, thereby avoiding costly medical care. The cognitive-behavioral intervention was not effective and therefore was not cost-effective for women. The advocacy training intervention averted only 0.019 infections (per 100 participants) and cost $465,994 per QALY saved.

Among male participants, the single-session, cognitive-behavioral, and advocacy training interventions averted 0.041, 0.087, and 0.138 infections per 100 participants, respectively. The corresponding cost-utility ratios were $26,305, $60,279, and $41,980 per QALY saved.

The goal of HIV prevention cost-effectiveness analysis is to determine the most efficient use of limited HIV prevention funds for a particular population group.[56] For women with mental illness, the single-session intervention evaluated by Kelly and colleagues was cost-saving, and therefore the most cost-effective of the four interventions examined in the Pinkerton *et al* and Johnson-Masotti *et al* analyses. To compare the relative cost-effectiveness of interventions for men with mental illness, Johnson-Masotti *et al* calculated incremental cost-utility ratios (additional cost per additional QALY saved by one intervention, relative to another) for the three Kelly *et al* interventions. Their results indicated that the cognitive-behavioral intervention cost about $91,000 more per QALY saved than the single-session intervention, and advocacy training cost approximately $11,000 more per QALY saved than the cognitive-behavioral intervention and $49,000 more per QALY saved than the single-session intervention. Because society generally is willing to spend at least $40,000 to $60,000 to save a QALY,[51,57-59] Johnson-Masotti *et al* concluded that the advocacy training intervention was the most cost-effective of the Kelly *et al* interventions for men with mental illness (the Otto Salaj *et al* intervention was not effective for men).

Discussion

Intervention Efficacy

The review of intervention efficacy indicated that the risk reduction interventions evaluated to date have had only limited success at helping people with severe mental illness reduce their HIV risk behavior. Most effect sizes indicating successful risk reduction were in the small or small to moderate range. However, some of the larger effect sizes were from smaller studies, and larger sample sizes generally reduce error in effect sizes estimates.[60] The largest trial conducted to date found small effect sizes for women, and no positive effects on risk behavior for men.[41]

With such a small sample of trials, it was not possible to associate the magnitude of effect size to other methodological characteristics such as intervention content. All of these trials had similar core intervention elements that went beyond simple HIV/AIDS education (i.e., exercises to sensitize participants to their risk of infection and enhance personal motivation to reduce risk, exercises to build interpersonal skills necessary for risk reduction), were conducted in group format, and required a relatively intense focus on HIV over multiple intervention sessions. It is certainly possible that other strategies may produce stronger risk reduction effects in this population, but the studies reviewed describe the limited universe of intervention approaches evaluated in controlled trials to date.

The observed negative effect sizes observed in Kelly *et al*[33] and Otto-Salaj *et al* [41] warrant discussion. For example, the cognitive-behavioral skills building condition (without advocacy training) in Kelly *et al* resulted in negative effect sizes compared to the one-session educational control condition.[33] Although there was an absolute increase in condom use and decrease in frequency of unprotected intercourse in this group from baseline to follow-up, the improvements were neither statistically significant nor greater than the behavior change observed in the one-session control group.[33]

Intervention Cost-Effectiveness

The two cost-effectiveness studies produced similarly mixed findings. Excluding intervention conditions that did not produce significant risk reduction effects, the calculated cost-utility ratios ranged from cost-saving (i.e., the cost-utility ratio was negative) to over $465,000 per QALY saved for female intervention participants, and from over $26,000 to nearly $42,000 per QALY saved for male participants. Kelly *et al* [33] single-session small group intervention was the most cost-effective prevention strategy for women, whereas the advocacy training program was judged to be most cost-effective intervention for men, provided that society is willing to spend the extra money (approximately $49,000) it costs to implement this program rather than the less costly and less effective single-session intervention.[45]

How do these cost-effectiveness results compare to other HIV prevention interventions for other populations of at-risk

adults? In general, the cost-effectiveness literature suggests that interventions to prevent sexual transmission of HIV can be extremely cost-effective and even cost-saving.[56,61] Small-group format, community level, and outreach HIV prevention interventions appear to be particularly cost-effective in preventing the spread of HIV infection among moderate to high-risk heterosexual adults.[62,63] Counseling and testing programs have also been shown to be cost-effective strategies for preventing HIV transmission among high-risk heterosexuals.[64]

Some of the interventions reviewed in this paper do not appear to be as cost-effective as alternative interventions for at-risk heterosexual adults, while others (such as the single-session small group intervention for women)[33] appear to be more cost-effective. However, cross-study comparisons of interventions for different populations can be misleading.[56] Intervention cost-effectiveness depends on the number of infections averted, which in turn depends not only on the sexual behavior changes reported by intervention participants, but also on pre-existing (baseline) HIV risk levels, on the prevalence of HIV infection among sex partners, and on the efficiency with which HIV is transmitted during male-female, female-male, and male-male intercourse. The primary objective of HIV prevention cost-effectiveness analysis is to identify the most cost-effective intervention for a particular population, once it has been determined that the population is in need of HIV prevention services.[56] The results of the Pinkerton *et al* [45] and Johnson-Masotti *et al* [46] studies demonstrate that cost-effective intervention strategies for adults with serious mental illness are available, regardless of how the cost-effectiveness of these strategies compares to the cost-effectiveness of interventions for other priority populations.

Several limitations of the two existing cost-effectiveness studies[45,46] deserve mention. First, in deriving the cost-utility ratios, they made use of standard values of the lifetime cost of treating HIV disease and the number of QALYs that are saved whenever an HIV infection is averted.[55] These values were based on health needs and prognoses of non-mentally ill persons, and might differ for persons with severe mental illness. There are reasons to believe that use of these standard values could discriminate against those with serious mental illness.[65]

Because cost data were not collected as part of the original intervention trial, intervention costs were ascertained retrospectively; as a consequence, unknown error could have been introduced in the cost estimates. The National Institute of Mental Health in the United States has recommended that researchers conduct prospective cost analyses in conjunction with future efficacy trials.[66] A second potential source of error was the self-reported behavioral data collected from the intervention participants,[34,67] as discussed further below. Uncertainty in key epidemiological parameters, such as the HIV prevalence in the community, could also have contributed to error in estimating the cost-utility ratios.

To model the impact of some of these sources of uncertainty, the two cost-effectiveness studies conducted multiple sensitivity analyses to determine whether errors in these values would substantially affect the policy implications of the main results. The sensitivity analyses indicated that the main results were fairly robust to changes in key parameter values in both studies. The policy implications of these results—that advocacy training was cost-effective for men, but not for women, and that the single-session intervention was cost-effective for women–were not affected by the different parameter values used. An additional source of uncertainty that is not adequately controlled for by the use of sensitivity analyses is the random sampling error arising from the small sample sizes involved in the current study; the impact of this source of error is not known.

Limitations of First Generation Prevention Efficacy Studies and Implications for Future Research

The first generation of randomized controlled intervention trials for people with severe and persistent mental had several design characteristics that are worthy of discussion and can be improved upon in future studies. First, sample sizes were small. This can be partially attributed to the fact that these were among the first trials and some were considered pilot studies for future, more elaborate intervention trials.[29,33,40] The largest study, in which 189 participants were randomly assigned to two groups, was the only study to include 30 or more participants in each group.[40] Given the heterogeneity of samples of people with severe and persistent mental illness, discussed in more detailed below, samples may need to be expanded to include sufficient numbers men and women with specific diagnoses or characteristics, or focused more specifically on people with particular psychiatric characteristics to reliably detect intervention effects.

Also related to the pilot nature of several studies, only two studies included time-matched comparison conditions.[33,41] The other studies either included a wait-list control group or a much briefer intervention as the comparison condition, which is an appropriate approach in a Phase I efficacy trial. However, study designs that do not control for participant contact allow the interpretation that risk reduction or increase in preventive behavior, as observed in the Susser *et al*,[42] Weinhardt *et al,*[25] and Kalichman *et al* [40] studies, may have been due to the increased attention given to the participants in the experimental conditions and not to effects specific to the interventions delivered.

Outcomes were based solely on the participants' self-reported sexual behavior, a practice that has been criticized even when used with samples not characterized by psychological impairment.[34,67] Although recent research indicates that psychiatric samples are capable of providing *reliable* retrospective reports of sexual behavior for reporting periods up to three months, it remains a concern that the *validity* of self-report data is not known conclusively.[68,69] This is true of HIV risk reduction research with other populations as well, because it is difficult to establish a ''gold standard'' with which to compare self-reports of behavior.[67,70] For example, even biological indicators, such

as recently acquired gonorrhea or chlamydia infections, do not allow a rigorous evaluation of the validity of the reports of *frequency* of sexual risk behavior because one can engage in risk behavior but not become infected, and conversely, an individual could become infected after only a single occasion of intercourse with an infected partner.

Further, to use incident STD infections as an outcome variable requires very large sample sizes to detect intervention effects, and STD infections may not be useful proxies for HIV infection.[71,72] In the future, investigators evaluating HIV risk reduction interventions in psychiatric samples may be best able to minimize the impact of this limitation by conducting thorough evaluations of the self-report outcome measures prior to use for outcome evaluation, or by using measures previously evaluated in similar samples.

Finally, all intervention studies reviewed in this paper enrolled people with a variety of psychiatric diagnoses, such as schizophrenia, schizoaffective disorder, bipolar disorder, and major depressive disorder. Although all studies indicated that each participants' impairment was severe enough to have required multiple previous hospitalizations and in most cases ongoing psychopharmacological treatment, it is likely that participants in each study had widely varying symptoms, levels of symptom severity, and functional ability. It may be the case that the interventions tested in these trials worked well for subgroups of participants, depending on their particular type and level of impairment, but not well for others. Different psychiatric illnesses may impact risk taking and self-care behavior in distinct ways. Based on the limited number of studies presented here, in the future, it may prove more effective to develop interventions for people with specific psychiatric diagnoses or clusters of symptoms rather than attempting to use a ''one size fits all'' approach with samples that are actually quite diverse.

The gender differences observed in the efficacy and cost-effectiveness studies highlight the importance of focusing on gender-specific issues when delivering HIV prevention interventions to men and women with severe mental illness. Possible explanations for the gender-related differences include the following. First, research has shown that women with severe mental illness are at increased risk for HIV because they experience sexual coercion, partner infidelity, difficulty in saying no to sexual relationships, and the need for economic assistance.[14] Safer sex negotiation skills training may have particularly benefited women in the first intervention, especially those who were sexually active. Previous research also has shown that alcohol and other drug use are associated with increased high-risk behavior.[73-75] In the Otto-Salaj *et al* study, the majority of men (but few women) reported having consumed drugs and alcohol in the previous three months.[41] Moreover, women in this study reported higher HIV risk behaviors at baseline than did the men. The different psychiatric diagnoses for the men and women in the study may have contributed to this difference in risk behavior.[19,24]

People with severe and persistent mental illness have a wide range of reasons for engaging in risk behavior, and although the intervention approaches used in the reviewed intervention studies were specifically chosen or tailored to address barriers to risk reduction in the severe and persistent mental illness, future interventions may need to be tailored further to individual circumstances. Interventions using formats that can more easily be adapted (i.e., individual approaches) to the wide range of problems and levels of functioning found among adults with severe mental illness may yield stronger results. Further, given that people with severe and persistent mental illness face challenges in multiple areas of functioning, it may be overly optimistic to expect that an intervention targeting only one aspect will have significant and long-lasting effects. Wider-reaching interventions may be necessary to have an appreciable impact on sexual risk behavior. Such interventions may include treatment for alcohol and drug use problems in conjunction with HIV risk reduction activities, social services such as housing placements and legal assistance, and use of an ongoing individualized case-management approach rather than the relatively brief group-based approaches used in the reviewed studies. It is clear that increased effort is needed to develop efficacious risk behavior reduction interventions and to identify the mediators and moderators of intervention efficacy in this population.

Summary

In summary, evidence from the few randomized controlled HIV risk reduction intervention trials conducted to date indicate that intensified efforts are needed to develop interventions that result in more consistent and long-term risk reduction among people with severe mental illness. The results of the available cost-effectiveness analyses indicate that interventions for this population can be highly cost-effective and even cost-saving.

The next generation of intervention research for people with severe mental illness, to advance the field, will need to significantly improve upon the designs and intervention strategies of the first generation. This topic is of considerable interest and importance and the marginal nature of the effects produced thus far clearly demonstrates that the scientific community needs to give this issue greater attention.

Appendix

Data Analytic Procedures

We searched the Medline, PsychInfo, and HealthStar databases for HIV risk reduction interventions for adults with mental illness that were evaluated in randomized clinical trials and published in the peer-reviewed scientific literature. This strategy resulted in the identification of five rigorously evaluated HIV prevention efficacy studies.

For each study, we computed a between-group effect size (Cohen's *d*) using the mean paired change score from baseline to the first follow-up assessment in each trial, such that a positive effect size indicates that the intervention group

reduced risk behavior or increased preventive behavior more than the control group.[76] We chose the first follow-up assessment because: (i) some trials included only one follow-up, and (ii) we sought to examine the maximal efficacy of the interventions, which tends to be most pronounced at earlier follow-ups.[77] Effect sizes were computed for each of the following outcomes when available: frequency of unprotected intercourse, frequency of protected intercourse, and number of sexual partners. All effect sizes were calculated such that a positive effect size indicates greater risk reduction (i.e., reduced unprotected intercourse, decrease in the number of sexual partners, or increase in condom use) in the intervention group relative to the control group. Effect sizes for each outcome were calculated separately for men and women when the data were available. Effect sizes are in standard deviation units and conventionally, an effect size *d* of ± 20 is small, a value of ±50 is medium, and values exceeding ±80 are large.[43]

The purpose of computing effect sizes for this review was to determine the direction and magnitude of effects in each study, thereby providing a more detailed analysis than the results of statistical significance tests presented in the original studies. Given the small number of randomized trials available, we did not seek to test formal models of effect size moderators or to statistically test studies against one another.

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