

# SCIENCE AND SUCCESS

Clinical Services and Contraceptive Access



Advocates for Youth



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**Advocates for Youth—Rights. Respect. Responsibility.®**

Advocates for Youth is dedicated to creating programs and advocating for policies that help young people make informed and responsible decisions about their reproductive and sexual health. Advocates provides information, training, and strategic assistance to youth-serving organizations, policy makers, youth activists, and the media in the United States and the developing world.

Written by Sue Alford, MLS and Barbara Huberman RN, Med.

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# Science and Success:

## Clinical Services and Contraceptive Access

### Introduction

Despite recent declines in teen pregnancy, U.S. teen birth and sexually transmitted infection (STI) rates remain among the highest in the western world. Given the need to focus limited prevention resources on effective programs, Advocates for Youth undertook exhaustive reviews of existing research to compile a list of the programs proven effective by rigorous evaluation and identified 24 programs that meet the criteria below.

**Criteria for Inclusion**—All 24 programs had evaluations that:

- Were published in peer-reviewed journals (a proxy for the quality of evaluation design).
- Used an experimental or quasi-experimental design, with treatment and control/comparison conditions.
- Included at least 100 young people in treatment and control / comparison groups, combined.
- Collected baseline and post-intervention data from both treatment and control/comparison groups.

Further, the evaluations either:

- Continued to collect data from both groups at three months or later after intervention,  
*and*
- Demonstrated that the program led to at least two positive behavior changes among program youth, relative to controls:
  - ◆ Postponement or delay of sexual initiation
  - ◆ Reduction in the frequency of sexual intercourse
  - ◆ Reduction in the number of sexual partners / increase in monogamy
  - ◆ Increase in the use, or consistency of use, of effective methods of contraception and/or condoms
  - ◆ Reduction in the incidence of unprotected sex.
- Or, showed program effectiveness in reducing pregnancy, STIs, or HIV in intervention youth, relative to controls.

Of the 24 science-based programs, seven are either based in a clinical setting or have a strong contraceptive access component. Descriptions of these programs follow.

**Table A. Effective Programs and Their Impact on Adolescents’ Risk for Pregnancy, HIV & STI Programs**

PROGRAMS	BEHAVIORAL OUTCOMES							HEALTH IM-PACTS		
	<i>Delayed Initiation of Sex</i>	<i>Reduced Frequency of Sex</i>	<i>Reduced Number of Sex Partners</i>	<i>Increased Monogamy</i>	<i>Reduced Incidence of Unprotected Sex</i>	<i>Increased Use of Condoms</i>	<i>Increased Use of Contraception</i>	<i>Increased Compliance with STI Treatment Protocols</i>	<i>Reduced Incidence of STIs</i>	<i>Decreased Number or Rate of Teen Pregnancy / Birth</i>
1. School/Community Program for Sexual Risk Reduction among Teens	★					★				★
2. Self Center (School-Linked Reproductive Health Center)	★				★		★			★
3. Children’s Aid Society—Carrera Program	★					★	★			★
4. SiHLE — STI & HIV Prevention for African American Teenage Women		★			★	★			★	★
5. Tailoring Family Planning Services to the Special Needs of Adolescents							★			★
6. HIV Risk Reduction for African American and Latina Adolescent Women			★		★				★	
7. Project SAFE: Sexual Awareness for Everyone		★		★	★			★	★	

Note: Blank boxes indicate either 1) that the program did not measure nor aim at this particular outcome/impact or 2) that the program did not achieve a significant positive outcome in regard to the particular behavior or impact.

**Table B. Effective Programs: Settings & Populations Served**

PROGRAMS	LOCALE			AGE RANGE				POPULATIONS			
	<i>Urban</i>	<i>Sub urban</i>	<i>Rural</i>	<i>Elementary</i>	<i>Jr. High</i>	<i>Sr. High</i>	<i>18-24</i>	<i>White</i>	<i>Black</i>	<i>Hispanic /Latino</i>	<i>Asian</i>
1. School/Community Program for Sexual Risk Reduction among Teens			★	★	★	★		★	★		
2. Self Center (School-Linked Reproductive Health Center)	★				★	★			★		
3. Children’s Aid Society—Carrera Program	★				★	★			★	★	
4. SiHLE — STI & HIV Prevention for African American Teenage Women	★	★				★			★		
5. Tailoring Family Planning Services to the Special Needs of Adolescents		★	★			★		★			
6. HIV Risk Reduction for African American and Latina Adolescent Women	★				★	★				★	★
7. Project SAFE: Sexual Awareness for Everyone	★					★	★			★	★



# School/Community Program for Sexual Risk Reduction among Teens

## Program Components

- Sex education integrated into biology, science, social studies, and other courses
- Graduate level sex education courses for teachers
- Training of peer educators
- School-based health clinic services, including contraceptive provision as well as referral and transportation to reproductive health care in the community
- Workshops to develop parents' and community leaders' skills as role models
- Media coverage of a spectrum of health topics

## For Use With

- Kindergarten through 12th grade
- Multiethnic youth\*
- Rural youth

## Evaluation Methodology

- Quasi-experimental design, including treatment and comparison conditions, in rural counties in South Carolina
- Rural young women, ages 14 to 17 (n≈4,800)
- Estimated pregnancy data (live births plus fetal deaths plus abortions) for the intervention county and three contiguous counties, compared prior to the program (1981-1982), during the two years of the program (1984-1986), and for two years post-program (1987-1988)

## Evaluation Findings

- Long-term: reduced teen pregnancy rate

## Replication Evaluation Methodology & Findings

- Quasi-experimental design, including treatment and comparison conditions
- Rural and urban students (n=1,714) in grades nine through 12 in two counties in Kansas during 1994-1996
- Delayed initiation of sexual intercourse
- Increased condom use (males only)

Evaluators' comments: *Our reanalysis strongly suggests that the incidence of adolescent pregnancies... decreased between 1984 and 1986 as a result of the overall efforts of the Denmark program... In 1987-1988, pregnancy rates returned to a higher level, probably because of both the cessation of provision of contraceptive counseling and supplies in school and the loss of momentum of the program.*

Koo, Dunteman, George, *et al*, 1994

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\* Populations in the evaluations include white and black youth.

## Program Description

This intensive, school-based intervention has the overall goal of reducing unintended teen pregnancy. Based on social learning theory and diffusion theory, its behavioral objectives include postponing the initiation of voluntary sexual intercourse among teens and promoting the consistent use of effective contraception, including condoms, among teens that choose to have sex.<sup>1,2</sup>

As originally implemented in Denmark, South Carolina, the program includes several components. Teachers are offered graduate level courses in sex education. Sex education is then integrated into the curriculum for all grades (kindergarten through 12th grade). The intervention offers mini-courses (five sessions of two hours each) for parents, clergy, and community leaders to improve their skills as role models. Students are trained to serve as peer educators. Local media reinforce messages about avoiding unintended pregnancy and highlight special, community events of the initiative. Finally, a school nurse provides contraceptive counseling, condoms to requesting students, and transportation to a local family planning clinic.<sup>1</sup>

## Evaluation Methodology

In the mid-1980s, the county was 58 percent black and 42 percent white, lacked public transportation, and was primarily agricultural. Little migration into or out of the county occurred. For evaluation, annual estimated pregnancy rates for the intervention portion of the county (western) were compared with the estimated rates for the non-intervention portion of the county (eastern) and for three other South Carolina counties with socio-demographic indicators similar to the target community. Trends in estimated pregnancy rates were then examined by comparing the average pregnancy rates for the pre-intervention years (1981-1982) with the average rates for the intervention years (1984-1986) and post-intervention years (1987-1988) and comparing changes from pre-intervention to post-intervention between areas.<sup>1</sup> A second evaluation, conducted in the early 1990s, re-examined the impact of the program by comparing pregnancy rates in the intervention community with rates in other portions of the county, and six more counties (contiguous and non-contiguous) that analysis had shown to be most similar to the intervention county.<sup>1</sup>

## Long-Term Impact

- **Reduced teen pregnancy rate**—Evaluation found that the pregnancy rates in the intervention portion of the county declined significantly as compared to pre-program levels (from 77 pregnancies per 1,000 women ages 14 through 17 in 1981-1982 to 37 per 1,000 women the same age in 1984-1986).<sup>1,2</sup>
- **Teen pregnancy rates in comparison counties**—When compared to the marked decline that occurred in the intervention portion of the county, no other county's pregnancy rate showed a similar, large decline. Pregnancy rates in the comparison counties ranged from 74 to 90 pregnancies per 1,000 women ages 14 through 17 in 1981-1982 and from 67 to 82 pregnancies per 1,000 women the same age in 1984-1986.<sup>1</sup>
- **Return to a higher teen pregnancy rate after some program components were discontinued**—Reanalysis showed that the pregnancy rate returned to a higher level (66 per 1,000 women ages 14 through 17) in 1987-1988, after the discontinuation of some program components, including the contraceptive services provided by the school nurse during the years 1984-1986.<sup>2</sup>

## Replication Evaluation Methodology

In Kansas in 1994-1996, evaluators measured the effects of a replication of the intervention in Geary and Franklin counties. Portions of Wichita were also included in the program, but not in the evaluation, because teenage sexual behavior data were not available for Wichita's youth. In Geary County, the population was 66 percent white, 23 percent black, six percent Hispanic, and four percent Asian. In Franklin County, the population was 97 percent white, two percent Hispanic, and one percent black. Data for Geary and Franklin counties on teen pregnancies and births were compared to data for 20 similar Kansas counties in 1991-1993 (pre-intervention years) and 1994-1996 (intervention years). Youth's sexual behaviors in the intervention counties were compared across the years, using self-reported data for high school students in both counties at the inception of the program (1994) to self-reported data for high school students at the end of the program in Geary County (1997) and near the end of the program in Franklin County (1996). For this later data, evaluators used responses to the 1993 Youth Risk Behavior Survey and the Adolescent Curriculum Evaluation, given in 1994, 1996, and 1997.<sup>3</sup>

## Replication Outcomes

### ■ Behaviors—

- ◆ **Delayed initiation of sexual intercourse**—In Geary County, students' reports of ever having had sex decreased significantly among males and females in ninth and 10th grades between 1994 and 1997 (down from 51 to 38 percent of females and 63 to 43 percent of males, respectively).<sup>3</sup>
- ◆ **Increased condom use**—In Franklin County, more male students in the upper grades reported using condoms in 1996 (55 percent) than in 1994 (39 percent).<sup>3</sup>

## For More Information or to Order, Contact

- *Sociometrics, Program Archive on Sexuality, Health & Adolescence*; Phone: 1.800.846.3475; Fax: 1.650.949.3299; E-mail: [pasha@socio.com](mailto:pasha@socio.com); Web: <http://www.socio.com>

# Self Center (School-Linked Reproductive Health Services)

## Program Components

- School-linked health center (SLHC) across the street from a high school and down the street from a junior high school
- Free reproductive and contraceptive health care at the SLHC
- SLHC staff working daily in participating schools
- SLHC staff providing sex education lessons in each homeroom and in the clinic
- Daily hours for individual and group counseling by social worker and/or nurse (SLHC staff) in the school health suite

## For Use With

- Junior and senior high school students
- Urban youth
- Black youth
- Economically disadvantaged youth

## Evaluation Methodology

- Quasi-experimental design, including treatment and comparison conditions, at four inner-city junior and senior high schools in Baltimore, Maryland
- Urban youth (n=3,646 at baseline; n=2,950 at final follow-up), in grades seven through 12
- Pretest in the fall and follow-up surveys each spring of the next three years

## Evaluation Findings

- Delayed initiation of sexual intercourse
- Increased use of reproductive health care prior to initiating sex
- Reduced incidence of unprotected sex
- Increased use of contraception
- Long-term: reduced teen pregnancy rate

Evaluators' comments: *The rapid effect on clinic use, exerted by an intervention program designed to supplement the basic sex education program already in place, suggests that it was the accessibility of the staff and of the clinic, rather than any "new" information about contraception that encouraged the students to obtain services.*

Zabin, Hirsch, Smith, *et al*, 1986

## Program Description

As originally implemented in Baltimore, Maryland, the program is an adolescent health clinic offering reproductive health care—including contraceptive counseling, pregnancy testing, and other medical services and referral—and located very near to junior and senior high schools. It is designed to provide year-round contraceptive and reproductive health services and education to students. In the model program, a team from the clinic, consisting of a nurse practitioner and a social worker, make presentations at least once a year in each homeroom. These discussions deal with services offered in the clinic and with other reproductive and sexual health topics. The clinic staff then spends several hours each day in the school health suite, available to students for counseling or group discussions. In the afternoon, these same health professionals provide services in the reproductive health clinic near the schools. Any student can drop in to talk, to receive counseling / education,

or to participate in group discussions. Staff places strong emphasis on developing personal responsibility, setting goals, and communicating with parents. Reproductive health services are available free of charge to students who enroll in the clinic and remain in school. This program is intended to augment basic sex education curricula.<sup>4</sup>

## Evaluation Methodology

In evaluation, 1,201 black students in the two participating schools were compared with 1,749 black students with similar backgrounds attending schools not participating in the program. At baseline, the socioeconomic status of participants and comparison youth was similar, and almost 90 percent of youth qualified for the school lunch program. Prior to baseline, almost 92 percent of males and 54 percent of females in ninth grade had initiated sex; about 47 percent of females in seventh and eighth grades had also initiated sex. Among sexually active youth, 56 percent of those in junior high and 73 percent of senior high students reported using contraception at most recent sex. Evaluation relied on self-administered student surveys—a pretest in the fall before the program began and follow-up surveys in the spring of the succeeding three years.<sup>4</sup>

## Outcomes

- **Knowledge**—Over the course of the program, the proportion of participating females who correctly identified the fertile period during the menstrual cycle increased significantly from 30 to 44 percent, versus an increase from 31 to 38 percent among comparison females.<sup>4</sup>
- **Attitudes and perceptions**—The proportion of participating females who believed that less effective contraceptive methods could prevent pregnancy dropped significantly from 38 to 24 percent, relative to a drop from 47 to 44 percent among comparison females. Among male participants, the proportion believing that less effective methods could prevent pregnancy dropped significantly from 53 to 34 percent, while the proportion of comparison males who believed in less effective methods rose from 50 to 60 percent.<sup>4</sup>
- **Behavior**—
  - ◆ **Delayed initiation of sexual intercourse**—Significantly more young women who were exposed to the program for three years delayed the initiation of sexual intercourse, by a median of seven months, compared to those not exposed to the program. At age 14, about two-thirds more teenage women had initiated sex before the program started as had done so after three years of exposure to the program. Delay in initiating sex was smaller for young women with only one or two years of exposure to the program.<sup>4</sup>
  - ◆ **Increased use of reproductive health care prior to initiating sex**—Significantly more program students attended a family planning clinic before initiating sex and during the first months of sexual activity, compared to non-program youth.<sup>4</sup>
  - ◆ **Reduced incidence of unprotected sex**—Use of no contraceptive method at most recent sex was reduced to extremely low levels among young women exposed to the program. Less than 20 percent of these young women failed to use contraception in the months following first coitus. This finding held even among seventh and eighth grade students, whose age is often associated with poor use of contraception. Among comparison young women, up to 49 percent reported no use of contraception.<sup>4</sup>
  - ◆ **Increased use of contraception**—Sexually active youth exposed to the program for two years were significantly more likely to report using birth control pills at most recent sex, compared to non-program youth. Program females' reports of pill use rose from 33 to 50 percent, while reports of pill use by comparison females rose only from 33 to 36 percent.<sup>4</sup>

## Long-Term Impact

- **Reduced teen pregnancy rate among high school females**—By the program's third and final year, the pregnancy rate among high school students in program schools had dropped by 30 percent, while it had risen by 58 percent among students in non-program schools.<sup>5</sup>
- **Reduced pregnancy rate among younger females**—Among the youngest students, the pregnancy rate decreased slightly in program schools while it increased dramatically in non-program schools.<sup>4,5</sup>

## For More Information, Contact

- **Dr. Laurie Schwab Zabin**, School of Hygiene & Public Health, Johns Hopkins University; Phone: 410.955.5753; Fax: 410.955.0792
- **Sociometrics, Program Archive on Sexuality, Health & Adolescence**; Phone: 1.800.846.3475; Fax: 1.650.949.3299; E-mail: [pasha@socio.com](mailto:pasha@socio.com); Web: <http://www.socio.com>

# Children’s Aid Society—Carrera Program

## Program Components

- Youth development program
- Daily after-school activities, lasting three to five hours, and including
  - ◆ Job club / career exploration
  - ◆ Academic tutoring and assistance
  - ◆ Comprehensive sex education, including information about abstinence and contraception
  - ◆ Arts workshops
  - ◆ Individual sports activities
- Summer program, offering enrichment activities, employment assistance, and tutoring
- Comprehensive health care, including primary, mental, dental, and reproductive health care
- Family involvement
- Interpersonal skills development
- Access to social services

## For Use With

- Youth at risk\*
- Socioeconomically disadvantaged youth
- Urban youth, ages 13 through 15
- Black and Hispanic youth

## Evaluation Methodology

- Experimental design, including treatment and control conditions, in seven community-based service agencies in New York City
- Urban youth ages 13 through 15 (n=600 at baseline; n=484 at three-year follow-up)
- Pre-test and annual follow-up in each of three succeeding years

## Evaluation Findings

- Delayed initiation of sexual intercourse (females only)
- Increased resistance to sexual pressure (females only)
- Increased use of dual methods of contraception (females only)
- Long-term: reduced rates of teen pregnancy

Evaluators’ comments: *Our study clearly documents the effectiveness among females of a comprehensive program to prevent adolescent pregnancy. Although our analyses cannot determine the relative importance of the model’s components, the philosophy, structure, and specific staff roles may each contribute to the successful long-term relationships that a large proportion of the young people formed with the program and its staff.*

Philliber, Williams, Herrling, *et al*, 2002

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\* Risk is defined in the evaluation of this program as “disadvantaged, inner-city populations” of youth who were not already enrolled in an after-school program and were neither pregnant nor parenting at enrollment.

## Program Description

This is a sex education, pregnancy prevention, and youth development program for urban youth considered to be at high risk. The comprehensive intervention rests on six principles: 1) staff treats young participants as if they were family; 2) staff views each young person as pure potential; 3) the program offers holistic services and comprehensive, integrated case management; 4) the program includes continuous, long-term contact with participants; 5) the program involves parents and family; and 6) all services are available under one roof in a non-punitive, gentle, generous, and forgiving environment. The program has five activity components and two service components. Activity components include 1) the job club—offering stipends, help with bank accounts, employment experience, and career awareness; 2) academics—including individual assessment, tutoring, PSAT and SAT preparation, and assistance with applying to colleges; 3) comprehensive family life and sexuality education; 4) arts—including weekly music, dance, writing, or drama workshops; and 5) individual sports activities that emphasize impulse control, such as squash, golf, and swimming. The two service components are 1) mental health care and 2) medical care, including reproductive health care, primary care, and dental care.<sup>6</sup>

Throughout the school year, program activities run all five weekdays, generally for about three hours per day. Participants are divided into groups which rotate among the five major activities offered. One group might receive sex education on Tuesdays and Thursdays, for example, while another group attends Job Club. On Monday and Wednesday, the groups would be reversed. Most students participate in sports and creative activities at least once a week and receive academic assistance daily. Over the summer, program activities include maintenance meetings to reinforce youth's sex education and academic skills. During the summer, participants also receive job assistance and participate in social events, recreational activities, and cultural trips.<sup>6</sup>

## Evaluation Methodology

A multi-site evaluation compared youth in the Children's Aid Society—Carrera Program to youth recruited at six other service agencies throughout New York City. Youth were randomly assigned to the Children's Aid Society—Carrera Program or to an alternative program. At most sites, the alternative was the agency's regular program for youth. Young people (n=484) ranged in age from 13 to 15. Fifty percent of participants were male. Among females, 54 percent of participants were black and 46 percent were Hispanic; among males, 47 percent were black and 53 percent were Hispanic. The majority of the youth (55 percent) lived in single parent homes. The program's effectiveness was assessed using annual surveys.<sup>6</sup>

## Outcomes

- **Knowledge**—Overall after three years, program participants' knowledge of sexual health issues rose by 22 percent, compared to 11 percent among control youth, a statistically significant difference. Male participants showed higher sexual health knowledge gains than did control males (18 and six percent, respectively).<sup>6</sup>
- **Behavior**—
  - ◆ **Delayed initiation of sexual intercourse**—Program young women were significantly less likely than control females to have ever had sex—46 percent had never had sex versus 34 percent of control females.<sup>6</sup>
  - ◆ **Increased resistance to sexual pressure**—Females in the program were significantly more likely than those in the control group to say they had successfully resisted pressure to have sex (75 percent and 36 percent, respectively).<sup>6</sup>
  - ◆ **Increased use of dual methods of contraception**—Sexually experienced program females were significantly more likely than control females to have used a condom along with a highly effective method of contraception (i.e., the pill, the injectable, or the implant) at most recent sex (36 percent and 20 percent, respectively).<sup>6</sup>
  - ◆ **Increased receipt of good health care**—Both male and female participants had significantly increased odds of receiving good health care. Among sexually experienced males, the proportion who had made a visit for reproductive health care was significantly higher among program than control males (74 and 46 percent, respectively).<sup>6</sup>

- ◆ **Other findings related to young men**—Overall, program males showed no positive, significant behavioral differences relative to control males, except increased receipt of good health care. On the other hand, program males were less likely than control males to report use of dual methods of contraception at most recent sex. Researchers speculated that the program effects may have been weaker among young men, in part because 1) young men who had initiated sex prior to enrolling in the program were the least likely to attend regularly; 2) strong social norms among these inner-city young males might stress the benefits of early sexual intercourse and parenthood; and 3) program males may not have repeated the program’s messages to their non-enrolled female partners. The data suggest that reaching young men sooner may strengthen outcomes, and, as a result, the Children’s Aid Society has begun implementing programs with 11- and 12-year-old youth.<sup>6</sup>

## Long-Term Impact

- **Reduced rates of teen pregnancy**—At third-year follow-up, females in the Children’s Aid Society—Carrera Program had significantly lower rates of pregnancy and births than did control females.<sup>6</sup>

## For More Information, Contact

- **Children’s Aid Society**, 105 East 22nd Street, New York, NY 10010; Phone: 212.949.4800; Web: <http://www.childrensaidsociety.org>

# SiHLE—STI & HIV Prevention for African American Teenage Women

## Program Components

- Community-based HIV prevention program for use in family medicine and health clinics
- Gender-specific and culturally tailored program
- Four, four-hour interactive group sessions, held on successive Saturdays
- Sessions utilizing poetry and artwork of African American women, role plays, and discussions, demonstrating use of a condom
- Health educator and peer educators (all trained, African American, and female)
- Compensation (\$25.00) for travel and child care

## For Use With

- Sexually active African American teenage women, ages 14 to 18

## Evaluation Methodology

- Experimental evaluation design with treatment and control conditions in Birmingham, AL
- Eligible African American adolescent females (n=522) seeking services at four community health agencies between December 1996 and April 1999 and randomly assigned to treatment (n=251) and control (n=271) conditions
- Data from baseline questionnaire, interview, demonstration of condom use skills, and STI testing
- Follow-up after six and 12 months

## Evaluation Findings

- Increased condom use
- Reduced incidence of unprotected sex
- Reduced number of new sex partners
- Reduced incidence of STIs
- Reduced incidence of pregnancy

## Program Description

This STI/HIV prevention intervention is based on social cognitive theory and theories of gender and power. The program is culturally and gender-specific for African American adolescent women at risk for negative sexual health outcomes. The program's designers worked in partnership with community African American female teens to develop the intervention and the study conditions. The intervention consists of four sessions, each lasting four hours and implemented on consecutive Saturdays at a community health clinic. The program is implemented by a trained health educator who is also female and African American and by two female African American peer educators. The peer educators model skills and promote group norms supportive of HIV prevention.<sup>7</sup>

*SiHLE* comes from a Swahili word for beauty and also is an acronym for sisters informing, healing, living, and empowering. Session one emphasizes ethnic and gender pride, encouraging participants to explore and discuss the joys and challenges of being an African American adolescent female and acknowledging the accomplishments of African American women through reading their poetry and framing their art. Session two enhances awareness of HIV risk reduction strategies, such as abstaining from sex, using condoms consistently, and having fewer sex partners. Session three uses role-plays and cognitive rehearsal to enhance the young women's confidence in their ability to initiate safer sex conversations with a partner, to negotiate safer sex, and/or to refuse unsafe sex. During session three, peer educators also discuss the importance of abstinence and consistent

condom use and model condom use skills. Session four emphasizes the importance of healthy relationships. The health educator and peer educators lead discussions in how unhealthy relationships can make it difficult to practice safer sex.<sup>7</sup>

## Evaluation Methodology

From December 1996 through April 1999, recruiters screened 1,130 self-identified African American adolescent females seeking health care services at any of four community health agencies. Of these, 609 (54 percent) met eligibility criteria for the study. Eligibility criteria included being African American and female, 14 to 18 years of age, having had vaginal intercourse in the preceding six months, and providing written, informed parental consent. [Among those not eligible, nearly 93 percent were not sexually experienced.] Of the 609 eligible adolescents, 522 agreed to participate in the study, completed baseline assessments, and were randomly assigned to treatment (n=251) or control (n=271) conditions. Treatment youth received the HIV intervention; control youth received a general health promotion program of equal length and duration (four, four-hour sessions). Each participant received \$25.00 as compensation for anticipated travel and child care expenses.<sup>7</sup>

Evaluators collected data at baseline and at six- and 12-month follow-up, each time from four sources. Participants completed a self-administered questionnaire on socio-demographics and psychosocial aspects of HIV preventive behaviors. A trained African American female health counselor then interviewed each participant to assess 1) sexual behaviors; and 2) condom use skills. Finally, participants provided two self-collected vaginal swab specimens, one to test for gonorrhea and chlamydia and the other, for trichomoniasis. Self-reported, consistent condom use in the 30 days prior to each assessment was the main outcome measure. Other self-reported sexual behaviors included incidence of protected and unprotected sex and a new partner in the 30 days preceding assessment. Self-reported pregnancy and STI incidence (determined by testing) were also assessed.<sup>7,8</sup>

At baseline, evaluators detected significant differences between the treatment and control conditions in terms of HIV-related sexual behaviors, and these were included as covariates in subsequent data analyses. [Covariates included: history of douching; gang involvement; alcohol use; nonconsensual sex; depression; having a new partner; desiring to be pregnant; and/or not attending school.] No significant differences were seen on socio-demographic characteristics, condom use, or other outcome measures. For example, the mean age of intervention participants was 15.99; that of control youth was 15.97. Forty-six percent of treatment youth had not completed 10th grade, compared to 49 percent of control youth; 18 and 18.5 percent, respectively, received public assistance; 74 and 72 percent, respectively, lived in a single parent home; 24 percent and 23 percent, respectively, had children. Thirty-eight percent of each group reported using a condom in the past 30 days; three and two percent, respectively, reported unprotected vaginal sex in the past thirty days. At baseline, 19 percent of treatment young women and 16 percent of controls tested positive for chlamydia; six and five percent, respectively, tested positive for gonorrhea; 13 and 12 percent, respectively, tested positive for trichomoniasis.<sup>7</sup>

Of the 251 participants assigned to the HIV intervention, 226 (90 percent) completed the six-month assessment and 219 (87 percent) completed the 12-month assessment. Of the 271 youth assigned to the control condition, 243 (90 percent) completed the six-month assessment and 241 (89 percent) completed the 12-month assessment. No differences in attrition were observed between study conditions at either the six-month or the 12-month assessment. Additionally, evaluators found no differences at either follow-up in: socio-demographic factors; or differences in baseline variables for study condition participants versus those lost to follow-up.<sup>7</sup>

## Outcomes

- **Increased condom use**—Intervention participants were more likely than controls to use condoms consistently in the 30 days preceding the six-month assessment (75 versus 58 percent;  $P=.06$ ), in the 30 days preceding the 12-month assessment (73 versus 57 percent;  $P=.02$ ), and during the entire 12 month period (odds ratio 2.01;  $P=.003$ ). Intervention participants were more likely than controls to report consistent condom use in the six months preceding the six month assessment (61 versus 43 percent;  $P=.001$ ) and in the six months preceding the 12-month assessment (58 versus 45 percent;  $P=.01$ ).<sup>7</sup>
- **Reduced incidence of unprotected sex**—Intervention participants were significantly less likely than controls to report unprotected sex in the 30 days prior to the six-month assessment (mean difference -1.82 versus 0.27; relative change -50.69;  $P=.046$ ).<sup>7</sup>

- **Reduced number of new sex partners**—Intervention participants were less likely than controls to report having a new sex partner in the 30 days preceding the six-month (three versus seven percent;  $P=.01$ ) and 12-month (four versus six percent;  $P=.01$ ) assessments.<sup>7</sup>
- **Reduced incidence of pregnancy**—Intervention participants were significantly less likely than controls to report a pregnancy in the six months after baseline (four versus seven percent;  $P=.04$ ) or in the 12 months after baseline (six versus nine percent;  $P=.06$ ).<sup>7</sup>
- **Reduced incidence of chlamydia**—Results of STD-specific analyses over the entire 12-month follow-up period, adjusting for baseline variable and covariates, suggested a treatment advantage in reducing chlamydia infections (OR 0.17;  $P=.04$ ). There were no observed treatment effects in reducing either gonorrhea or trichomoniasis. Evaluators suggest that the small STI treatment effects are due, in part, to the relatively small number of incident STIs and to missing data for some covariates.<sup>7</sup>

## For More Information, Contact

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# Tailoring Family Planning Services to the Special Needs of Adolescents

## Program Components

- Clinic-based education, counseling, and contraceptive services for adolescents
- Tailoring to meet the psychosocial information, reassurance, and support needs of youth under age 18
- Personal Information Form, completed by the teenage client
- Increased counseling time, including an extra five minutes for initial phone contact and an extra 15 to 20 minutes for one-on-one counseling
- Lasting six weeks, including two-part first appointment and follow-up appointment
- First session divided into two visits: one-on-one education and counseling in the first, including use of videos and other visual aids; medical services in the second, no more than two weeks later for examination and contraceptive prescription
- Follow-up appointment six weeks after the second half of the first session
- Encouragement of involvement by parents, friends, and/or partner, while ensuring one-on-one counseling for the client
- Reassurance as to confidentiality and strict maintenance of confidentiality
- Training for counselor educators as well as for regular clinic staff
- Training on adolescent psychosocial development for every staff member

## For Use With

- Suburban and rural, white, teenage women, age 17 and younger
- Developmentally delayed teens

## Evaluation Methodology

Quasi-experimental design, with treatment and comparison groups of non-randomly selected patients in six pre-selected family planning clinics in non-metropolitan Pennsylvania

- Females ages 17 or younger (n=1,256) divided into treatment (n=518) and control (n=738) groups
- Survey at the initial visits and follow-up visit (Knowledge Quiz), at the conclusion of the index visit (Patient Satisfaction Survey), follow-up survey completed by staff at all follow-up visits (Method-Use Questionnaire), and No-Show/Continuation Report, completed for all clients enrolled in the study
- Data collected at enrollment, at three to eight months after baseline, and at nine to 20 months after baseline

## Evaluation Findings

- Increased use of contraception
- Decreased pregnancy rate

Evaluators' comments: *Tailoring family planning services to the special psychosocial needs of teenagers has beneficial effects on most outcomes and undesirable effects on none... The cost of the intervention was in the extra personnel time needed to counsel and instruct patients... However, the extra time spent on counseling and education and the earlier return visit represented an investment that paid off in patients' improved skill and success in using contraceptives.*

Winter, Breckenmaker, 1991

## Program Description

This pregnancy prevention protocol for family planning clinics and other reproductive health care providers works to meet the special psychosocial needs of family planning clients who are under the age of 18. Such special needs include 1) education geared to an adolescent's level of cognitive development; 2) reassurance of confidentiality; 3) extra time for counseling, especially in order to address the teen's concerns about contraceptive methods or to answer questions regarding difficulties encountered with a contraceptive method; 4) information and reassurance regarding medical exams; and 5) medical services. A Personal Information Form, completed by the teenage client, helps counselors identify young women who are at higher risk for pregnancy than are other young women. These include young women who: are age 17 or younger; are developmentally delayed; have no plans for the future; believe that a pregnancy would be okay; lack parental support; have sexual intercourse infrequently; are involved in short-term relationships; or do not initiate the clinic visit themselves. The Personal Information Form also allows the teen to identify worries or fears related to her visit or to using contraception, so that the counselor can discuss these issues with the teen.<sup>9</sup>

The teenage woman has longer than usual with a counselor for one-on-one education about contraception and sexual health. She returns within two weeks for the second half of the initial visit—at which time, the teen receives medical services, such as pelvic exam and/or pregnancy and STI tests and a prescription for the method of contraception she has chosen. She is also scheduled for another return visit in six weeks, at which time she can ask questions and discuss with a counselor any problems she has encountered with her chosen contraceptive method. The teen is encouraged to make appointments for additional return visits at about six months and one year in the future.<sup>9</sup>

## Evaluation Methodology

The evaluation was designed to assess three broad components of the intervention: 1) the knowledge that clients acquired; 2) their feelings about the clinic; and 3) their experience with family planning—particularly their use of contraception and contraceptive continuation and whether they experienced unintended pregnancy. Four survey tools provided data—the Knowledge Quiz, the Patient Satisfaction Survey, The Method-Use Questionnaire, and the No-Show/Continuation Report.<sup>9</sup>

The intervention was evaluated using a pretest/posttest design with intervention and non-intervention groups of non-randomly selected clients in six family planning clinics. During a two-month baseline phase, six clinics administered the Patient Satisfaction Survey and the Knowledge Quiz. At the end of this phase, staff from the three clinics designated as experimental sites attended a two-day training. During the next six months, clients attending the experimental sites received services as outlined by the experimental protocols. Clients included both first-time visitors and those making an annual (repeat) visit. The three comparison clinics continued their usual service delivery practices. Clients filled out forms at both experimental and comparison clinics at six months and one year after each client's index visit.<sup>9</sup>

Adolescent females, ages 17 and under, participated in the study (n=1,261 total; n=251 enrolled at baseline; and n=1,010 enrolled during the treatment phase). A few 18-year-old women were enrolled if counselors felt they were developmentally delayed or at especial risk for unintended pregnancy for other reasons. Overall, 62 percent of participants were making their first visit to a family planning clinic while the rest were making an annual (repeat) visit. Almost all clients were white; one percent was black and less than one percent was Hispanic. More than 40 percent were age 17; almost 34 percent were age 16; about 16 percent were age 15. About 22 percent were Roman Catholic, the largest single religious affiliation in the sample and reflective of the community demographic.<sup>9</sup>

## Outcomes

- **Knowledge**—Analysis showed that knowledge scores were initially high at both experimental and control sites and that contraceptive knowledge of clients improved more across time at experimental than at control sites (scores rose from 83 to 87 at experimental sites while holding steady at 82 at control sites).<sup>9</sup>
- **Behavior Outcomes**—
  - ◆ **Contraceptive use, original method**—Clients at experimental sites were significantly more likely at six-month follow-up to be still using their initial contraceptive method, relative to clients from comparison sites (92 versus 85 percent, respectively). The difference was even larger for clients for

whom the index visit was a first-ever visit for family planning (95 versus 83 percent, respectively). At 12-month follow-up, original method use remained significantly higher among clients from experimental sites relative to clients from comparison sites (90 versus 81 percent, respectively).<sup>9</sup>

- ◆ **Contraceptive use, any method**—Clients at experimental sites were significantly more likely to report use of any method at six-month follow-up, compared to clients from comparison sites (97 versus 92 percent, respectively). At 12-month follow-up, use of any method remained higher among clients from experimental sites than from comparison sites, but the difference was no longer statistically significant.<sup>9</sup>
- ◆ **Contraceptive continuation among clients experiencing method problems**—Clients who had problems with their contraceptive method were significantly more likely at experimental sites than at comparison sites to report continuing their method (79 versus 56 percent). The percentage difference was even more significant among those whose index visit was their first-ever family planning visit (83 versus 55 percent). The percentage of clients experiencing method difficulties and continuing use of the method remained significantly higher among those from experimental sites than comparison sites at 12-month follow-up (71 versus 40 percent).<sup>9</sup>

■ **Long-Term Impact**—Pregnancy rates were calculated in two ways: as a proportion of the continuing sample (n=740) and as a proportion of treatment phase sample (n=1,010). The 45 pregnancies identified among study participants, both experimental and comparison, represent 5.4 percent of the continuation sample and 4.5 percent of the treatment sample. With considerable consistency, the pregnancy rate among clients from the experimental sites was lower than that among clients at the comparison sites. Significant findings include the following:

- ◆ Four percent of continuing clients from experimental sites had a pregnancy versus eight percent at comparison sites;<sup>9</sup>
- ◆ Three percent of all clients from experimental sites had a pregnancy versus six percent at comparison sites;<sup>9</sup>
- ◆ Three percent of continuing 16- to 17-year-old clients at experimental sites had a pregnancy, versus eight percent at comparison sites;<sup>9</sup> and
- ◆ Nearly three percent of all 16- to 17-year-old clients at experimental sites had a pregnancy, versus nearly six percent at comparison sites.<sup>9</sup>

## For More Information or to Order, Contact

- **Sociometrics, Program Archive on Sexuality, Health & Adolescence**; Phone: 1.800.846.3475; Fax: 1.650.949.3299; E-mail: [pasha@socio.com](mailto:pasha@socio.com); Web: <http://www.socio.com>

# HIV Risk Reduction for African American and Latina Adolescent Women

## Program Components

- Clinic-based HIV-risk reduction program
- Culturally appropriate and gender specific program
- Single 250-minute (four and one-quarter hours) group session
- Interactive exercises, discussions, games, and experiential activities
- 8-hour training for facilitators

## For Use With

- Urban African American adolescent females
- Urban adolescent Latinas

## Evaluation Methodology

- Experimental evaluation design with two randomized treatment conditions and one control condition
- Sexually active clients (n=682) at an adolescent medicine clinic randomly assigned to skills-based treatment (n=235), information-based treatment (n=228), and health-promotion control (n=219) conditions
- Baseline data and follow-up at three, six, and 12 months after the intervention

## Evaluation Findings

- Reduced incidence of unprotected sexual intercourse
- Reduced number of sexual partners
- Reduced incidence of STIs

Evaluators' comments: *In the present study, the effects of the intervention were significant primarily at 12-month follow-up, not at shorter-term follow-ups. Such a delayed effect has been observed in other prevention trials. One possible explanation for why the magnitude of intervention effects might increase at later follow-ups is that people have difficulty introducing safer-sex practices into existing relationships. As they become involved with new partners over time, they are able to implement those practices. Hence, intervention effects on behavior are larger at longer-term follow-up. ... [From the results of this intervention] it cannot be assumed that an intervention developed for one ethnic group will be ineffective with another group.*

Jemmott, Jemmott, Braverman *et al*, 2005

## Program Description

The skills-based HIV and STI risk reduction intervention is based in cognitive behavioral theories and formative research. Designed for use in an adolescent medicine clinic that also provides young clients with confidential and free family planning services, the program teaches young women skills necessary to use condoms. In particular, it illustrates correct condom use, and depicts effective condom-use negotiation with a sexual partner. In addition to providing accurate information, it also addresses personal vulnerability and the heightened HIV risk facing young, inner-city Latinas and African American women. It addresses barriers to condom use, including negative beliefs and alcohol and drug use as well as ways to surmount these barriers. Most importantly, the young women practice handling condoms correctly on anatomical models and engage in role plays to increase their partner negotiation skills.<sup>10</sup>

## Evaluation Methodology

Evaluators tested the effects of the skills-based intervention in relation to an information-based HIV prevention intervention and to a generalized health promotion intervention. Participants had volunteered for a women's health project designed to reduce young women's risk of eventually developing serious health problems like heart disease, cancer, and AIDS. Each was reimbursed up to \$120 (\$40 for completing the intervention and pre- and post-intervention questionnaires; \$25 for the three- and the six-month follow-up; and \$30 for the 12-month follow-up). The young women completed a confidential, self-administered questionnaire immediately before and after the intervention and at three, six, and 12 months later. All questionnaires assessed sexual behavior and variables on demographics and conceptual mediators. Biological specimens for STI testing were collected at baseline and at 6- and 12-month follow-up.<sup>10</sup>

Participants were 682 sexually experienced African American (n=463) and Latina (n=219) young women, ages 12 to 19 who were family planning clients at an adolescent medicine clinic within a children's hospital that served low-income, inner-city youth in Philadelphia PA. Of all the adolescents (n=1,150) eligible for the study, 59 percent chose to participate, including a greater percentage of eligible African Americans than Latinas (69 versus 46 percent, respectively;  $P \leq .001$ ). Participants were also somewhat younger than non-participants (15.5 versus 16.1 years;  $P \leq .001$ ). Participants and eligible non-participants did not differ in STI prevalence at baseline.<sup>10</sup>

At baseline, 87 percent of respondents reported sexual intercourse, about 52 percent reported unprotected sexual intercourse, and 16 percent reported sexual intercourse with multiple partners in the previous three months. Ten percent of respondents had at least one child and 22 percent tested positive for gonorrhea, chlamydia, or trichomoniasis. Less than one percent reported having same-gender sexual relationships (0.4 percent) or using injection drugs (0.6 percent).<sup>10</sup>

Ninety-eight percent of participants attended at least one follow-up; 94 percent, the 3-month; 93 percent, the six-month; and 89 percent, the 12-month follow-up. There were few significant differences between those who returned for follow-up and those did not. Non-returnees: reported more frequent sex at baseline (mean, 3.44 versus 0.40;  $P \leq .001$ ) and more unprotected sex while intoxicated (mean 0.94 versus 0.24;  $P \leq .001$ ); were more likely to be Latina than African American (96 versus 99 percent;  $P = .04$ ); and were less likely to live with their mother (94 versus 99 percent;  $P = .001$ ). At follow-up, evaluators found were no significant differences between adolescents assigned to the information-based HIV/STI prevention condition and to the health promotion control condition.<sup>10</sup>

## Outcomes

- **Reduced incidence of unprotected sexual intercourse**—By 12-month follow-up, participants in the skills-based intervention reported significantly fewer days in the past three months when they had sex without using a condom, compared to either the information-based or the health promotion condition (2.27 days versus 4.04 [ $P = .03$ ] and 5.05 [ $P = .002$ ], respectively). In addition, young women in the skills-based intervention reported significantly fewer days when they had unprotected sex while using drugs or alcohol, compared to those in the health promotion condition (0.1 days versus 0.22 days;  $P = .02$ ).<sup>10</sup>
- **Reduced number of sex partners**—By 12-month follow-up, a significantly smaller proportion of participants in the skills-based intervention reported multiple sex partners in the previous three months compared to youth in the health promotion condition (seven percent versus 17 percent, respectively;  $P = .002$ ).<sup>10</sup>
- **Reduced incidence of STIs**—By 12-month follow-up, a significantly smaller proportion of participants in the skills-based intervention tested positive for STIs compared to youth in the health promotion condition (mean 11 percent versus 18 percent, respectively;  $P = .05$ ).<sup>10</sup>

**Note:** There were no significant differences in outcomes related to frequency of unprotected sex, number of sex partners, or rates of STIs by intervention at the three- or six-month follow-up.

## For More Information, Contact

- **Select Media;** Phone: 1.800.707.6334; Web: <http://www.selectmedia.org>
- For educator training, contact **ETR Associates;** Phone: 1.800.321.4407; Fax: 1.800.435.8433; Web: <http://www.etr.org>

# Project SAFE—Sexual Awareness for Everyone

## Program Components

- STI clinic-based behavioral intervention to reduce risk for HIV
- Culturally and gender specific intervention
- STI screening, counseling, and treatment
- Three small group sessions once a week for consecutive weeks and each lasting three to four hours, focusing on: 1) recognizing risk; 2) committing to change; and 3) building skills.
- Interactive teaching, including games, discussion, role plays, and behavior modeling
- Follow-up screening visits at six and 12-months after baseline as well as whenever symptoms or concerns about re-infection arise
- Trained facilitators of the same gender and race/ethnicity as participants
- Optional support groups meeting once a month for five months

## For Use With

- African American women, ages 15 through 24
- Latinas, ages 15 through 24

## Evaluation Methodology

### Evaluation of Project SAFE

- Experimental evaluation using a randomized controlled trial with treatment (n=313) and control (n=304) conditions
- Baseline data on African American (n=193) and English-speaking Mexican-American (n=424) women
- Follow-up at six- and 12-months post intervention

### Evaluation of Project SAFE-2

- Experimental evaluation with two treatment conditions (n=237 standard intervention; n=262 enhanced intervention) and one control condition (n=276)
- Baseline data on English-speaking Mexican-American (n=585) and African American (n=190) women
- Follow-up at six-, 12-, 18-, and 24-months after baseline

## Evaluation Findings

- Increased monogamy (Project SAFE-2)
- Reduced number of new sexual partners (both)
- Reduced incidence of unprotected sex (Project SAFE)
- Increased compliance with STI treatment protocols (both)
- Reduced incidence of STIs (both)

Evaluators' comments: *Despite substantial observed ethnic differences in attitudes, behaviors, and re-infection rates, the cognitive-behavioral intervention used in Project SAFE resulted in similar, proportionate reductions in the rate of re-infection among both ethnic groups, comparing study women with control women. This accomplishment is encouraging, in light of the disproportionate burden of sexually transmitted disease borne by low-income minority populations in the United States.*

Korte, Shain, Holden *et al*, 2004

## Program Description

This gender specific and culture specific behavioral intervention is based on cognitive behavioral theories, including the Health Belief Model, self-efficacy theory, diffusion theory, and decision-making models. It conforms to the stages of the AIDS Risk Reduction Model. The intervention consists of three multi-component sessions, each lasting three to four hours. Participants (ranging from three to 12 in a group) and a female facilitator (of the same race or ethnicity as participants) meet once a week for three consecutive weeks. Contents of the culture specific interventions are the same, although emphases and cultural cues vary. Highly trained facilitators provide information and also actively involve participants in lively and open discussions and games as well as in watching videos, modeling behaviors, and participating in role plays. Facilitators encourage participants to identify realistic risk-reduction strategies within the context of their own life and values. Discussion covers abstinence, mutual monogamy, correct and consistent condom use, full compliance with STI treatment protocols, and reducing the number of one's sex partners. In addition, participants are also encouraged to continue with optional support groups in meeting in five once-a-month sessions.<sup>11,12</sup>

In addition to the multi-component sessions, participants receive screening and treatment for STIs along with routine follow-up appointments at six, 12, 18, and 24 months after the baseline screening as well as encouragement to come in for screening whenever symptoms of STIs arise.<sup>11,12</sup>

## Evaluation Methodology

### Project SAFE

Participants were recruited from public health clinics in San Antonio, Texas. They were African American and Latino women who had a non-viral STI, such as chlamydia, gonorrhea, syphilis, or trichomoniasis. All participants spoke English. After giving informed consent, participants were interviewed and received baseline examination, screening for STIs, treatment where necessary, and counseling. At this point, participants were randomly divided into treatment and control conditions. Controls received standard STI counseling, lasting about 15 minutes, provided by nurse clinicians and conforming to guidelines issued by the Centers for Disease Control & Prevention. Participants, whether treatment or control, also received follow-up appointments for six and 12 months later and encouragement to come in if and when they experienced STI symptoms or feared re-infection. Participants received \$25.00 for their initial visit and for their six-month visit; they received \$50.00 for the 12-month visit.<sup>11</sup>

Seventy-one percent of participants were younger than age 24; the mean age of intervention group was 21.8 years and that of the control group was 21.3 years. Monthly income for the intervention group was a mean of \$243.00 while that of the control group was \$267.00. Women's mean educational attainment was 10.8 years in both groups. Seventy percent of participants were Mexican American (70 percent of intervention group and 68 percent of control group); the rest of the women were African American (30 and 32 percent, respectively). At baseline, 28 percent of women in the intervention group and 33 percent of the control group were pregnant. There were no significant differences at baseline between intervention and control group participants in the proportion infected with various STIs. Among the intervention group, 21 percent were infected with gonorrhea, 67 percent with chlamydia, 26 percent with trichomoniasis, and six percent with syphilis. Among the control group, 21 percent were infected with gonorrhea, 71 percent with chlamydia, 21 percent with trichomoniasis, and six percent with syphilis.<sup>11</sup>

After stratification according to race/ethnicity, a total of 424 Mexican American and 193 African American women were randomly assigned to study (n=313) or control (n=304) conditions. Rates of participation among the study group were 90 percent for the first session, 82 percent for at least two sessions, and 75 percent for all three sessions. Enrollment began in January 1993 and ended in July 1994. Six- and 12-month retention rates were 82 percent at six months (84 percent of study group; 80 percent of controls; total=508); and 89 percent at 12 months (91 percent of study group; 87 percent of controls; total=549). Twenty-six women with six-month visits were lost to follow-up at 12 months, while 67 women who missed the six-month screening returned at 12 months. Repeat screening for chlamydia and gonorrhea were also performed at a total of 260 problem visits. The analysis included 509 women at six months, 545 at 12 months, and 549 for the total study period. Behavioral analysis included results for 477 women who attended both follow-up visits. Rates of loss at follow-up did not differ significantly between study and control groups for any subgroup analysis.<sup>11</sup>

## Project SAFE-2

The evaluation protocol was nearly the same as in the first Project SAFE except that there were two treatment conditions (with and without optional support group meetings). All Mexican American and African American women diagnosed with gonorrhea, chlamydia, syphilis, or trichomoniasis in public health clinics were referred to the study for potential participation. Eligible, English speaking women of reproductive age (15 to 45 years old) were offered enrollment. Fourteen-year-old women were enrolled only at the specific request of the Health Department or their guardians and with special IRB permission. Researchers unexpectedly enrolled a much higher proportion of alcoholics and drug addicts in this study than in the previous study. Substance users were not excluded unless they under age 18, used hard drugs, and had dropped out of middle or high school. Women with only two of these three risk factors were still allowed to enroll. Young teens, ages 14 and 15, who had been sexually abused were allowed to participate but were excluded from analysis. Fifty-three enrolled women were later declared ineligible because of: protocol violations (n=5); severe mental illness (n=2); criminal activity in the clinic (n=1); being sexually abused 14- to 15-year-olds (n=16); or 14- to 17-year-old dropout users of hard drugs (n=29).<sup>12</sup>

A total of 585 Mexican American and 190 African American women were randomly assigned to enhanced intervention (Project Safe-2; n=262; with follow-up for a full two years), standard intervention (Project SAFE; n=237; with follow-up for one year), or a control group (n=276). All participants received follow-up appointments for six, 12, 18, and 24 months later and were encouraged to come in if and when they experienced STI symptoms or feared re-infection. Participants received \$25.00 for their initial and their six-month visits; they received \$15.00 for the 18-month visit and \$50.00 for each of the two annual visits (12 and 24 months).<sup>12</sup>

Enrollment began in March 1996 and ended in June 1998. Of 1,271 potentially eligible women 33 percent declined to participate. Intervention show rates (before the six-month visit) were 96 percent for at least one session, 92 percent for at least two sessions, and 86 percent for all three sessions. Among women assigned to the enhanced intervention, 63 percent chose not to attend the optional support groups; however, 37 percent attended at least one session prior to their six-month visit and 26 percent attended two or more sessions. Twelve-month and 24-month retention rates (based on 775 eligible women) were both 91 percent (n=709 and 707, respectively). No group differences in retention rates were detected although, within the enhanced intervention group, women who attended support groups had higher retention rates than those who did not attend (96 versus 84 percent,  $P=0.004$ ). Support-group non-attendees subsequently lost to follow-up (compared to non-attendees who were retained in the program) were more likely to have had more than one partner at baseline ( $P\leq 0.06$ ) and to have had syphilis ( $P\leq 0.001$ ).<sup>12</sup>

Low levels of income and education characterized the study participants; 53 percent were under age 20 and 85 percent under age 25. Less than 10 percent were married and over 60 percent had more than one partner in the previous year. Most importantly and despite random assignment, one or both intervention groups had a higher percentage of women who were under age 20, were in high substance risk categories, and/or had multiple additional screenings for gonorrhea and/or chlamydia. Support group attendees, compared to non-attendees, had less education (10.1 versus 10.7 years;  $P\leq 0.02$ ), were more likely to be young (62 versus 50 percent;  $P=0.056$ ), and were likely to report three or more partners in the previous three (13 versus five percent;  $P\leq 0.03$ ) and six month periods (27 versus 13 percent;  $P=0.007$ ).<sup>12</sup>

## Outcomes

- **Increased monogamy**—In Project SAFE-2, significantly more participants in the enhanced intervention group (especially support group attendees) and standard intervention group had only one partner during the entire study, compared to control group participants. Specifically, 37 percent of enhanced intervention participants and 39 percent of support group attendees had only one partner throughout the study compared to 24 percent of controls. Among standard intervention participants, 31 percent reported only one partner during the entire two-year period.<sup>12</sup>
- **Reduced number of sex partners**—In Project SAFE, significantly fewer women in the intervention group than in the control group reported multiple partners ( $P=0.004$ ). Specifically, nearly 68 percent of women in the intervention group reported no partner or only one partner in the 12 months after baseline compared to 56 percent of women in the control group. Nearly 33 percent of women in the intervention group reported more than one sexual partner, compared to 44 percent in the control group.<sup>11</sup>

In Project SAFE-2, significantly fewer women in the standard and enhanced intervention groups than in the control group reported multiple partners in any follow-up year ( $P=0.004$ ). Specifically, 43, 43, and 55 percent of participants, respectively, reported more than one sexual partner in year one. In year two, 38, 36, and 51 percent, respectively, reported more than one sexual partner. During the two-year period, 69, 63, and 76 percent ( $P\leq 0.052$ ,  $0.003$ ), respectively, reported more than one sexual partner.<sup>12</sup>

- **Reduced incidence of unprotected sex**—In Project SAFE, significantly fewer women in the intervention group than in the control group reported multiple acts of unprotected sexual intercourse ( $P=0.03$ ). Specifically, 30 percent of women in the intervention group reported fewer than five acts of unprotected sex in the three months preceding each follow-up appointment, compared to 20 percent of women in the control group. Of those reporting five or more acts of unprotected sex, the proportions were 70 and 80 percent, respectively.<sup>11</sup>
- **Compliance with treatment protocols**—In Project SAFE, significantly fewer women in the intervention group than controls were noncompliant with treatment protocols ( $P\leq 0.001$ ). Specifically, 84 percent of women in the intervention group were in compliance with treatment protocols, compared to 72 percent of the control group. Noncompliance with treatment protocols was defined as having sex with an untreated or incompletely treated partner, having multiple partners, and having five or more acts of unprotected sex during the three-month period preceding each follow-up visit. Follow-up analysis showed that women in mutually non-monogamous unions and who had sex with partners who were untreated or incompletely treated were also 13 times more likely to have an STI infection than those who were monogamous and who complied with treatment protocols.<sup>11,13</sup>

In Project SAFE-2, significantly more women in the both the standard and enhanced intervention groups than in the control group were compliant with treatment protocols (92, 90, and 82 percent, respectively;  $P\leq 0.001$  and  $P\leq 0.01$ , respectively for standard and enhanced interventions compared to controls). Noncompliance with treatment protocols was defined as having sex with an untreated or incompletely treated partner.<sup>12</sup>

## Long-Term Outcomes

- **Reduced incidence of STI infection**—In Project SAFE, women in the intervention group were significantly less likely than those in the control group to have gonorrhea or chlamydia infections at six months after baseline ( $P=0.05$ ), at between six and 12 months ( $P=0.008$ ) after baseline, and from entry through 12 months ( $P=0.004$ ).<sup>11</sup> The infection rate in the intervention group was 34 percent less than in the control group at six months, 49 percent less at 12 months, and 38 percent less overall.<sup>11,13,14</sup>

In Project SAFE-2, women in both the enhanced and standard interventions were significantly less likely at all intervals to be infected with either gonorrhea or chlamydia. Over the two-year study period, women in the enhanced and standard interventions, respectively, were 41 and 34 percent less likely to be infected than were controls ( $P\leq 0.001$ ,  $P\leq 0.008$ , respectively). Additionally, enhanced and standard intervention participants were significantly less likely than controls to be infected in year one (43 and 41 percent less likely;  $P=0.004$ ,  $0.006$ , respectively) and in year two (36 and 36 percent less likely;  $P\leq 0.03$ ,  $0.03$ , respectively).<sup>12</sup>

**Note:** Analysis of the effects of attending support group indicated that both attendees and non-attendees were less likely than controls to be infected with gonorrhea or chlamydia (45 and 37 percent less likely;  $P\leq 0.004$ ,  $0.01$ , respectively). In year two, attendees were 42 percent less likely than controls to be infected ( $P\leq 0.05$ ) whereas differences between non-attendees and controls did not reach statistical significance.<sup>12</sup>

**Note on Project SAFE:** When the evaluators looked at racial/ethnic differences in regard to risk and protective behaviors of women in the intervention and control groups, they found that the intervention was equally effective with both groups (OR=0.58 and 0.54, respectively). African American women reported more douching after sex, less mutual monogamy, and more rapid partner turnover. However, Mexican American women appeared slightly more likely to have sex with an untreated partner. There were no other differences in sexual behaviors likely to lead to STIs. A consistent pattern emerged in which most sexual risk behaviors were less common in intervention group participants than in control participants, regardless of their race/ethnicity.<sup>11,13</sup>

## For More Information or to Order, Contact

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