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SEPA STARTER KIT



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SEPA Implementation Manual

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WHAT IS THE PURPOSE OF THIS STARTER KIT?

This starter kit serves two purposes. The first is to provide information to agency leadership and members of the Board of Directors to help them decide which interventions they want included in the agency's portfolio of HIV prevention programs. The starter kit provides information to inform decisions about intervention selection, often referred to as adoption. This information can help agencies determine if SEPA is appropriate for them to implement with the at-risk female populations they serve.

The second purpose of this starter kit is to help agencies that are funded to deliver SEPA with planning and pre-implementation activities that need to be accomplished before client enrollment. Accomplishing these activities as soon as possible can help minimize delays in implementation, particularly if there is a wait for facilitator trainings or if other situations cause delays in starting the intervention.



INTRODUCTION TO SEPA

Latinas and HIV Risk

Many factors place women at risk of HIV infection, including limited recognition of partners' risky behaviors, inequality in relationships with men, biological vulnerability, substance misuse, and socioeconomic status. Additional risk factors among Latinas include social and cultural influences, such as traditional sex role socialization; domestic violence; limited exposure to sex and health education; and low awareness of risk.

Effective HIV prevention interventions for at-risk women are critically important. Research shows that HIV-infected women suffer worse psychosocial outcomes than men living with HIV, including poorer perceived self-concept; more external locus of control; and higher rates of anxiety, depression, and suicidal ideation after diagnosis. ¹

To increase awareness and reduce behaviors that put Latinas at risk of contracting HIV, SEPA — Salud, Educación, Prevención, Autocuidado or Health, Education, Prevention, Self-care — was developed and evaluated by Dr. Nilda Peragallo, dean of the School of Nursing and Health Studies at the University of Miami. ²

¹ Gielen AC, McDonnell KA, O'Campo PJ, Burke JG. Suicide risk and mental health indicators: do they differ by abuse and HIV status? *Women's Health Issues*. 2005;15(2):89-95.

² Peragallo, N, DeForge, B, O'Campo, P, Lee, S, Kim, Y, Cianelli, R, & Ferrer, L. A randomized clinical trial of an HIV-risk reduction intervention among low-income Latina women. *Nursing Research*. 2005; 54(2): 108-118.



Overview of SEPA

SEPA is a small group-level, evidence-based HIV/AIDS behavior change intervention for heterosexually active Hispanic women/Latinas³ between the ages of 18 and 44 at risk for HIV and STD infection due to unprotected sex with male partners.

SEPA consists of six two-hour sessions that include presentations; group discussions; and practice exercises on male and female condom use, condom negotiation, and assertive communication. Session content covers HIV and STD transmission and prevention, male and female reproductive anatomy, human sexuality, interpersonal communications, and domestic and intimate partner violence. The six sessions of SEPA are:

- Session 1: The Impact of HIV and AIDS on Our Community
- Session 2: HIV and AIDS, Other Sexually Transmitted Diseases, Human Anatomy, and Human Sexuality
- Session 3: How to Prevent HIV and Other Sexually Transmitted Diseases
- Session 4: Ways to Improve Communication with Our Partners
- Session 5: Relationship Violence, HIV Risk, and Safety Measures
- Session 6: Commencement and Welcome to a Brighter Future

Who Should Participate in SEPA?

Women are eligible to participate in SEPA if, during the six months prior to enrollment, they had unprotected vaginal or anal sex with a man of unknown serostatus or a man living with HIV, and/or if they were treated for an STD during the previous six months. The intervention does not address the specific prevention needs of commercial sex workers, injection drug users, or women with substance misuse problems. Participants should understand and be able to speak English.

³ For brevity, we refer to SEPA clients as “Latinas.”



As previously noted, SEPA was developed for Latinas between the ages of 18 and 44 who are at risk of HIV and STD infection due to unprotected sex. Although the intervention's efficacy trial included Mexican and Puerto Rican women, researchers believe that SEPA can be of benefit to at-risk women of diverse races and ethnicity if their prevention needs can be addressed by SEPA's activities. This means that SEPA can be adapted for women who are not Hispanic or Latina if they are in need of information on HIV and STD prevention and domestic violence, and if they need to strengthen their skills in communication with male partners, condom use, and condom negotiation. An in-depth discussion of adaptation appears under "Getting Started."

What Are The Benefits Of SEPA?

Agencies, clients, and the Latino community can all benefit from SEPA. By implementing SEPA, agencies know they provide HIV prevention that works to reduce risky sexual behavior. CDC considers SEPA an evidence-based intervention. This means research has demonstrated that the intervention was efficacious – that is, it produced significant reductions in sexual behaviors that put Latinas at risk for infection with the virus that causes AIDS. Women who participate in SEPA benefit because they learn how to protect their health and improve relationships with partners through skill-building activities on condom use and condom negotiation with male partners. When women in the community are healthy and there are reduced rates of HIV and STDs, the entire Latino community benefits.

The Science Behind SEPA

The Original Research

SEPA was developed and refined using a variety of research methods to ensure that the program is empirically based. The first study tested the appropriateness of an HIV risk assessment interview for use with a multi-ethnic community in Chicago. The interview was originally developed by Dr.



Nilda Peragallo and used with Puerto Ricans living on the east coast. The Chicago study identified the importance of partner communication and intimacy for understanding the context for AIDS risk reduction among Latinas in Chicago. A second study provided in-depth information about partner communication and related issues essential for the development of the intervention. Finally, a three-phase pilot study developed a culturally appropriate intervention, tested pre- and post-test tools that captured culturally relevant HIV risk behaviors and associated factors, and conducted a process evaluation to establish the feasibility and acceptability of the intervention.

Once pilot research was completed, a randomized clinical trial (RO1 NR04746-04; Nilda Peragallo P.I.) funded by the National Institutes of Health was conducted in Chicago between 1999 and 2001. The trial used a pre-test and post-tests immediately after completion of the intervention and at three- and six-month intervals after baseline to measure client outcomes.

Mexican and Puerto Rican women aged 18 to 44 (N=657) who reported sexual activity during the previous three months were recruited and randomly assigned to the intervention and control groups.

Latinas who were bilingual, bicultural, and certified by the American Red Cross as HIV counselors and instructors in English and Spanish facilitated the intervention. Acculturation and HIV-risk-related outcomes were examined. Findings indicated that SEPA was effective in reducing high-risk sexual behaviors among low-income Mexican and Puerto Rican women living in Chicago.

Compared to members of the control group 4.5⁴ months after the intervention, SEPA participants showed significant increases in:

- HIV knowledge

⁴ Intervention determinants during past 3 months were measured at 6 weeks, and 3 and 6 months after baseline, which translates to immediate post-intervention and approximately 1.5 and 4.5 months after intervention.



- Communication with partners about HIV issues
- Risk-reduction behavioral intentions
- Condom use⁵

In addition, SEPA participants had significant decreases in perceived barriers to condom use.

The Theory Basis of SEPA

Designed to help Latinas build the skills necessary for behavioral changes that lead to more healthy relationships and safer sex, SEPA is based on Social Cognitive Theory.⁶ The theory suggests that behavior change requires more than just increasing knowledge of HIV transmission and the benefits of condom use. Rather, the adoption of healthy and safer sex behaviors is developed through interaction between person, behavior, and others in the environment. According to Social Cognitive Theory, performance of a behavior is a function of outcome expectancies (expectations of more positive than negative outcomes) and self-efficacy (confidence in the ability to perform a behavior). SEPA enables participants to build self-efficacy through practice and role-playing exercises. Participants learn the importance of condom use and negotiation and are taught the skills needed to enhance their confidence in their ability to successfully perform the behaviors.

⁵ Sex behaviors during past 3 months (including percent of times having vaginal, anal, or oral sex while using a condom) were measured at 6 weeks, and 3 and 6 months after baseline, which translates to immediate post-intervention and approximately 1.5 and 4.5 months after intervention.

⁶ Bandura, A. (1986). *Social foundations of thought and action: A social cognitive theory* Englewood Cliffs, NJ: Prentice-Hall.

Core Elements and Key Characteristics

Core Elements



Core elements are intervention components that must be maintained without alteration to help ensure program success. The seven core elements of SEPA are described below.



Core Element #1

Provide culturally and linguistically appropriate information to sexually active women at risk of acquiring HIV from unprotected sex with male partners in interactive, small-group sessions that focus on:

- HIV and STD transmission and prevention;
- human sexuality and male and female anatomy;
- interpersonal communications; and
- relationship violence.

This core element demonstrates the need for

- factual information presented in understandable ways that are consistent with participants' cultural values and beliefs; and
- shared learning through group discussion and activities.



Core Element #2

Incorporate skill-building activities into sessions to enhance women's self-efficacy for safer sex behaviors, including demonstrations and practice exercises on male and female condom use and role-plays on assertive communication with sex partners, including condom negotiation.

Core element #2 illustrates the use of Social Cognitive Theory because skill-building exercises are used to enhance self-efficacy, a fundamental determinant of behavior change.



Core Element #3

Build self-efficacy and knowledge for safer sex behaviors, improved communication with partners, and violence management through homework exercises and the sharing of personal experiences.

This core element reinforces the need for skill-building activities and learning by sharing personal experiences with members of the group and new information with members of the community. This core element draws from Social Cognitive Theory by emphasizing skill building and modeling.

Participants serve as models when they carry out homework assignments and share knowledge gained with friends and family in the community. It also reinforces the importance of sharing, belonging, and accomplishment as supports for self-efficacy and behavior change.



Core Element #4

Show a culturally appropriate video during the first session that portrays the effects of HIV and AIDS on members of the target population and discuss what is communicated about the impact of HIV and AIDS on the community, including impacts on families and women.

Core element #4 underscores the importance of using culturally congruent materials and the importance of discussing HIV and AIDS in a culturally relevant context.



Core Element #5

Use a female facilitator who speaks and understands the language of participants. The facilitator should not be a peer of participants but someone who is an experienced professional in health education, disease prevention, and risk reduction.

This core element emphasizes the need for trained and culturally competent staff. It recognizes the importance of matching facilitators who are content or subject matter experts in HIV and STD prevention with the target population. Core element #5 illustrates the concept of modeling in Social Cognitive Theory. There is the expectation that participants will learn by modeling the skills displayed by the facilitator.



Core Element #6

Ask participants to write thank-you notes to fellow participants and pledge their commitment to community health during the final session. Present a certificate to each participant who attends at least half of the sessions.

This core element reflects the tenets of Social Cognitive Theory by enhancing participants' self-efficacy through a sense of accomplishment and by fostering the positive outcome expectancy of helping to improve community health.



Core Element #7

Conduct no more than two sessions each week.

Core element #7 also relates to Social Cognitive Theory because we want SEPA participants to practice what they learn and to share information with others. If sessions are held without time between them for participants to do homework, core element #3 will be violated.

Key Characteristics



Key characteristics are intervention activities, delivery methods, or other aspects of the intervention that are not required and can be changed, or adapted, to meet agency or target population needs. Even if an agency does not adapt an evidence-based intervention, it is sound practice to adhere to as many key characteristics as possible because they contribute to the success of evidence-based interventions. SEPA's key characteristics are:

-  Foster assertiveness and self-esteem among participants through education, skill-building exercises, and discussion, and by addressing cultural norms within the Hispanic/Latino community.
-  Explore the dynamics of sexual relationships in the context of Hispanic/Latino culture.
-  Address perceived personal risk and susceptibility to infection with HIV and other sexually transmitted diseases as well as perceived barriers to remaining HIV negative.
-  Use the DVD “Mi Hermano” to stimulate discussion about the impact of HIV and AIDS on Hispanic/Latino families, women’s HIV risk, and the need to practice safer sex behaviors.
-  Provide transportation assistance and childcare services to participants. Provide light refreshments at each session.
-  Employ facilitators who are certified by the American Red Cross as HIV instructors or who have attended HIV prevention training sponsored by a health department or prevention training center. Employ facilitators who have received training in domestic violence and sexual violence.



-  Invite a former SEPA participant who completed all sessions to assist with such activities as room setup and the distribution of handout materials.
-  After Session 1, groups should not meet with fewer than two or more than 12 participants.
-  Ask participants to complete an evaluation after each session.

Behavior Change Logic Model

A behavior change logic model connects the theoretical components of an intervention with intervention activities to explain the intervention's effect on immediate and intermediate outcomes, including changes in behavior. Logic models help intervention developers and implementation staff understand the relationships among the target population's risk factors and behaviors, the theory that provides the behavior change logic of the intervention, intervention activities, and intended outcomes.

A behavior change logic model is a conceptual framework that visually delineates the:

- intent of the intervention (what is the target population, what behavioral problem is to be changed, and what change is intended?);
- determinants of behavior change for the target population;
- intervention activities expected to lead to behavior change; and
- anticipated outcomes.

The intent of the intervention is presented in the logic model's problem statement. The problem statement depicts the target population, the behavior that places this population at risk for HIV, and factors that contribute to risk. For SEPA, the target population is Latinas between the ages of 18 and 44 who have unprotected sex with male partners. Factors that contribute to this



behavior include social and cultural issues, such as gender inequality, and gender role socialization.

The determinants of behavior change relate to SEPA's theoretical basis in Social Cognitive Theory. For intervention design, determinants help identify activities that can contribute to behavior change. As noted above, skill-building exercises that can enhance self-efficacy and belief in one's capacity to take action increase the likelihood that behavior change will occur.

The behavioral determinants for SEPA are knowledge, self-efficacy, attitudes, and intentions; the behavior change logic model shows which activities in each of SEPA's six sessions correspond to these determinants of behavior change.

Immediate outcomes correspond to activities and determinants of behavior change and are believed to contribute to the behavior changes noted under intermediate outcomes. The intent is for SEPA participants to successfully negotiate condom use and consistently and correctly use condoms with their sex partners.

SEPA's behavior change logic model appears below. A general information flyer for SEPA appears in Appendix A.



Behavior Change Logic Model for SEPA

Problem Statement			
<p>Hispanic women/Latinas between the ages of 18 and 44 are at risk for HIV and STD infection when they have unprotected sex with male partners. Explanations for unprotected sex include lack of knowledge about sexually transmitted diseases, including HIV; negative attitudes toward condoms; a shortage of effective communication skills; reluctance to discuss condoms due to fear of violence from male partners; the absence of skills to negotiate condom use and to use male and female condoms correctly; and low risk-reduction behavioral intentions. Research suggests that social and cultural factors, such as gender inequality and gender role socialization, including Machismo and Marianismo, are associated with insufficient knowledge about HIV and STD transmission and prevention and inadequate ability to communicate effectively with male partners. These factors are likely sources of disempowerment that contribute to HIV risk among Hispanic women/Latinas.</p>			
Behavior Change Logic⁷			
Behavioral Determinants <i>Correspond to risk or contextual factors</i>	Activities <i>To address behavioral determinants</i>	Outcomes <i>Expected changes as a result of activities targeting behavioral determinants</i>	
		Immediate Outcomes: Expected to occur immediately following SEPA	Intermediate Outcomes: Expected to occur between one and six months after completing SEPA
1. Knowledge (knowledge of HIV transmission, prevention, and treatment)	Session 1: The Impact of HIV and AIDS on Our Community <u>Topics:</u> HIV transmission, perinatal prevention, testing for HIV infection <u>Activities:</u> Watch DVD, presentations, discussion; activities correspond to behavioral determinants 1, 2, and 4	Increases in: <ul style="list-style-type: none"> • HIV knowledge • Favorable attitudes toward condom use • Self-efficacy in 	Increases in: <ul style="list-style-type: none"> • Correct and consistent condom use with sex partners of unknown HIV serostatus during vaginal and anal sex

⁷ SEPA is grounded in Social Cognitive Theory.



<p>2. Attitudes (attitudes toward condom use)</p> <p>3. Self-efficacy (sense of competence in condom negotiation, condom use, and assertive communication skills)</p> <p>4. Intentions (intentions to reduce risks and practice safer sex)</p>	<p>Session 2: HIV and AIDS, Other Sexually Transmitted Diseases (STDs), Human Anatomy, and Human Sexuality <u>Topics:</u> Rumors and truths about HIV and AIDS; human reproductive anatomy; human sexuality; STD transmission, testing, and treatment <u>Activities:</u> Presentations and discussion; activities correspond to behavioral determinants 1, 2, and 4</p> <p>Session 3: How To Prevent HIV and Other Sexually Transmitted Diseases <u>Topics:</u> ABCs of HIV prevention, the truth about condoms, the male condom, the female condom <u>Activities:</u> Presentations, discussion, demonstrations, and skill-building exercises on male and female condom use; activities correspond to behavioral determinants 1, 2, 3, and 4</p> <p>Session 4: Ways to Improve Communication With Our Partners <u>Topics:</u> Self-esteem and how it affects relationships, types of communication, assertive communication, condom negotiation <u>Activities:</u> Presentations, discussion, role-playing on assertive communication and condom negotiation; activities correspond to behavioral determinants 1, 2, 3, and 4</p>	<p>partner communication skills, condom use skills, and condom negotiation skills</p> <ul style="list-style-type: none"> • Risk-reduction behavioral intentions 	
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	<p>Session 5: Relationship Violence, HIV Risk, and Safety Measures <u>Topics:</u> Conflict resolution in healthy relationships, sexual violence, intimate partner violence, impact of violence on families, safety measures and action planning <u>Activities:</u> Presentations, discussion, and role-playing on assertive communication with partners and conflict resolution; activities correspond to behavioral determinants 1, 2, 3, and 4</p> <p>Session 6: Commencement and Welcome to a Brighter Future <u>Topics:</u> Session reviews, sharing what we have learned <u>Activities:</u> Presentations, discussion, pledge of commitment to a healthier community, thank-you notes, and presentation of certificates; activities correspond to behavioral determinants 1, 2, 3, and 4</p>		
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GETTING STARTED

It takes time to adequately prepare for and successfully implement an evidence-based HIV prevention intervention. It also takes persistence and commitment to keep the program running successfully. Before implementing SEPA, know what pre-implementation activities need to take place.

Pre-implementation activities are planning and preparation actions that should occur before clients attend the first session of SEPA. It may take up to six months before agencies are ready to implement the intervention. The discussion that follows addresses agency capacity, staffing and budgeting, client recruitment and retention, and adaptation, and provides a suggested timeline for pre-implementation activities.

Agency Capacity to Implement SEPA

If you have received funding from the CDC or another source to implement SEPA, your funder believes you have the capacity to conduct the intervention. However, if you are reviewing SEPA materials to learn about the intervention and whether you want to pursue funding for implementation, you can assess your agency's capacity by referring to the table on the following pages. The criteria listed are examples of criteria used by funding agencies to assess applicants for funding.

Even if you have funding for SEPA, you can enhance your agency's success in serving clients by continuing to strengthen its capacity. You may want to discuss this table with your board of directors and with staff to identify ways to build an even better agency.



Agency Capacity to Implement SEPA: Criteria to Assess Capacity, Evidence for Criteria, and Explanations

Criterion	Evidence	Explanation
Written mission statement	<ul style="list-style-type: none"> Mission statement is visibly posted in agency 	<ul style="list-style-type: none"> Mission statement references target population and the goals of programs and services Outcomes of SEPA are consistent with the agency's mission
Written organization chart	<ul style="list-style-type: none"> Organization chart is complete and up to date 	<ul style="list-style-type: none"> Agency organization reflects clear lines of authority and responsibility Staffing is adequate for the number of services the agency provides and for monitoring and evaluation and quality assurance activities
Actively engaged board of directors	<ul style="list-style-type: none"> Minutes of board meetings By-laws and policies 	<ul style="list-style-type: none"> Board members provide financial support to the agency Board members have skills or expertise in fundraising, behavioral and prevention science, research and evaluation, quality assurance, cultural competence, and the needs of target populations, including Latinas Board members express commitment to evidence-based practice
Sound fiscal management	<ul style="list-style-type: none"> Reports of financial statements audits 	<ul style="list-style-type: none"> There are multiple and multi-year funding sources Financial management system allows agency to track staff time and costs for specific interventions and across multiple funding sources
Staffing and leadership	<ul style="list-style-type: none"> Records of staff turnover and new hires Minutes of board meetings 	<ul style="list-style-type: none"> Senior staff articulate a consistent management philosophy and demonstrate cultural competence in hiring and programs On average, staff tenure exceeds three years
History of providing services to target populations	<ul style="list-style-type: none"> Process monitoring data Reports prepared for funders and board of directors 	<ul style="list-style-type: none"> Reports indicate ability to recruit and retain clients who are members of identified target populations, including English-speaking Latinas

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Criterion	Evidence	Explanation
Track record of program monitoring and evaluation	<ul style="list-style-type: none"> Monitoring and evaluation plans Confidential client-level reporting of data Monitoring and evaluation reports 	<ul style="list-style-type: none"> Agency uses Specific, Measurable, Attainable, Realistic, and Time-based (SMART) objectives and/or program performance indicators for monitoring and evaluation Agency shares monitoring and evaluation reports with board of directors Agency implements changes based on monitoring and evaluation findings
Track record of quality assurance activities	<ul style="list-style-type: none"> Quality assurance plan Quality assurance reports 	<ul style="list-style-type: none"> Agency shares quality assurance reports with board of directors Agency implements changes based on quality assurance findings
Active client advisory committee	<ul style="list-style-type: none"> Notes of client advisory committee meetings 	<ul style="list-style-type: none"> There is a client advisory committee that helps staff understand risk-taking behaviors among target populations and contexts for those behaviors Committee helps staff identify recruitment methods and outreach locations for potential clients Committee reviews intervention protocols, especially concerning cultural competence
Written intervention protocols	<ul style="list-style-type: none"> Written protocols exist for behavior change interventions and public health strategies 	<ul style="list-style-type: none"> Protocols demonstrate understanding of how behavior change theory and determinants of behavior change are incorporated into intervention activities; protocols identify core elements and required activities for behavior change interventions

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Criterion	Evidence	Explanation
Written agency-wide policies and procedures	<ul style="list-style-type: none"> Written documents are current and copies are given to all staff 	<ul style="list-style-type: none"> Policies and procedures are in place for human resource/personnel issues and such topics as client confidentiality, staff safety, and use of client incentives
System for tracking referrals	<ul style="list-style-type: none"> Written policies and procedures on making and tracking referrals exist, are shared with staff, and are reviewed on a regular basis 	<ul style="list-style-type: none"> Client charts reflect staff understanding of how to conduct needs assessments and make appropriate referrals Process-monitoring data and written reports document how staff monitor referrals
Ongoing staff training and development	<ul style="list-style-type: none"> Staff training and development policies exist There are records of training and development activities that have taken place in the past 12 months 	<ul style="list-style-type: none"> Agency takes advantage of training, capacity-building, and technical assistance opportunities, and policies support staff development
Collaborations and partnerships with other organizations, including the state health department	<ul style="list-style-type: none"> Notes from meetings Reports of activities 	<ul style="list-style-type: none"> Collaborations and partnerships address the needs of target populations Collaborations and partnerships support the implementation of evidence-based interventions Working relationships with the health department address evidence-based practice, including funding opportunities, training, and capacity-building assistance

Stakeholder Involvement



Community-based organizations need active stakeholder involvement to enhance the success of their programs. In addition to clients, staff, and the agency's board of directors, other individuals and agencies have a stake in the success of SEPA. Examples of other stakeholders include agencies that serve the needs of Latinas, such as social service and health care providers; owners of local businesses; and community advocates. Stakeholders may support SEPA by:

- providing financial support to the agency
- referring at-risk Latinas to the intervention
- serving as a resource to which you can refer participants
- joining your community advisory board
- assisting with advertising or otherwise marketing the intervention
- donating refreshments and incentives to bolster client participation
- maximizing public support for the intervention

Always remember that clients of the interventions you deliver are your primary stakeholders. This means it is incumbent upon all staff to provide high-quality services and interventions and for agency leadership to support staff development and efforts to continually improve the organization's capacity to achieve success.

Important efforts to enhance the success of SEPA are monitoring and evaluation (M&E) and quality assurance. These activities are discussed in SEPA's Implementation Manual. Key stakeholders with an interest in these efforts and their results include the agency's board of directors and funders.



Community-based organizations that are funded by the CDC need to remember that their state health department (or other health department funded by the CDC) is a stakeholder. Share M&E findings with the health department and consider meeting with the department's community planning group for HIV prevention to discuss the intervention and such issues as client recruitment and retention.

Implementation Summary

An Implementation Summary is a conceptual framework that visually depicts and summarizes how a behavior change intervention is to be implemented or put into practice. In other words, an Implementation Summary depicts in summary fashion the programmatic requirements necessary for implementation of an intervention.

An Implementation Summary relates the **inputs** (resources) that must be secured, developed, and put into use to carry out implementation activities. It also describes the **outputs** (programmatic deliverables or products) that result when implementation activities are conducted.

The Implementation Summary depicted below is a tool that can help with planning. This summary is a companion to the behavior change logic model. By reviewing these models, you will better understand how SEPA is designed to bring about behavior change in clients and what needs to be accomplished to operationalize the behavior change logic. The basic information in the Implementation Summary can be expanded to inform decisions about the intervention's budget, implementation timelines, quality assurance activities, and monitoring and evaluation.

One pre-implementation activity is to review the list of inputs in the Implementation Summary to check that all inputs have been included in your budget for SEPA and that they are in place before implementation begins.



SEPA IMPLEMENTATION SUMMARY

<p style="text-align: center;">INPUTS</p> <p><i>Inputs are the resources needed to operate a program and conduct intervention activities.</i></p>	<p style="text-align: center;">ACTIVITIES</p> <p><i>Activities are the actions conducted to implement an intervention.</i></p>	<p style="text-align: center;">OUTPUTS</p> <p><i>Outputs are the deliverables or products that result when activities are conducted. Outputs provide evidence of service delivery.</i></p>
<ul style="list-style-type: none"> ▪ Bilingual (Spanish and English) Latina with skills and experience in health education, risk reduction, and disease prevention to serve as SEPA facilitator ▪ Heterosexually active Latinas between the ages of 18 and 44 at risk of HIV infection due to unprotected sex with male partners (eligible women) ▪ Agency policies, plans, and procedures applicable to SEPA (e.g., policy on client confidentiality, policy on working with women who are victims of domestic violence, monitoring and evaluation and quality assurance guides) ▪ SEPA Implementation Manual with Facilitators Guide, Participant Workbook, and client recruitment and retention plan ▪ SEPA budget (see discussion of costs in 	<p style="text-align: center;">Pre-Implementation/Preparation Activities</p> <ul style="list-style-type: none"> ▪ Hire (as needed) bilingual (Spanish and English) Latina with skills and experience in health education, risk reduction, and disease prevention to serve as Project SEPA facilitator ▪ Arrange training on SEPA for facilitator ▪ Determine schedule for group sessions and number of cycles per project year based on intervention budget ▪ Write and implement client recruitment and retention plan and monitoring and evaluation and quality assurance guides <p style="text-align: center;">SEPA Intervention Activities</p> <ul style="list-style-type: none"> ▪ Conduct six session intervention with groups of Latinas ranging in size from eight to 12 participants according to SEPA Implementation Manual and Facilitators Guide ▪ Discuss the impact of HIV and AIDS on the Latino community, human sexuality, male and female anatomy, HIV and STD transmission and prevention, and HIV 	<ul style="list-style-type: none"> ▪ Number of cycles of SEPA conducted during project year ▪ Number of eligible women who attended at least one SEPA session during project year ▪ Percent of eligible women who completed all six intervention sessions during project year ▪ Percent of eligible women who completed at least half but not all sessions during project year ▪ Percent of eligible women who completed less than half of the six sessions during project year ▪ Percent of SEPA budget obligated by end of project year

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<p style="text-align: center;">INPUTS</p> <p><i>Inputs are the resources needed to operate a program and conduct intervention activities.</i></p>	<p style="text-align: center;">ACTIVITIES</p> <p><i>Activities are the actions conducted to implement an intervention.</i></p>	<p style="text-align: center;">OUTPUTS</p> <p><i>Outputs are the deliverables or products that result when activities are conducted. Outputs provide evidence of service delivery.</i></p>
<p>this Starter Kit)</p> <ul style="list-style-type: none"> ▪ Equipment and supplies not included in intervention package: <ul style="list-style-type: none"> ○ LCD player, laptop computer, and screen ○ Anatomical figures for condom use demonstrations ○ Male latex condoms ○ Female condoms ○ Magazines for creation of collage for “How Can You Tell if Someone Has HIV” activity 	<ul style="list-style-type: none"> ▪ testing ▪ Demonstrate and practice the use of male and female condoms ▪ Identify and discuss characteristics of healthy heterosexual relationships ▪ Practice assertive communication ▪ Carry out condom negotiation role-playing exercises ▪ Describe and discuss safety measures in the event of domestic violence ▪ Discuss experiences with and outcomes of homework assignments ▪ Write notes of gratitude to fellow participants and pledge commitment to community health 	

Staffing



To successfully conduct SEPA, an agency must have qualified staff. Although the facilitator has a crucial role in implementing the intervention, managerial, program, and support staff also play important roles. For example, skilled and culturally competent outreach staff are needed to describe SEPA to potential clients and recruit those who are eligible. Monitoring and evaluation (M&E) and quality assurance (QA) staff who understand the behavior change logic of the intervention and the importance of program fidelity are needed. These individuals should possess requisite skills and expertise in writing M&E and QA plans and such activities as data collection and management and program oversight. Prevention program management staff are critical to the success of SEPA because they are in positions to provide the resources, training, supervision, agency capacity development, and public support needed to deliver effective client services.

As required by core element 5, the facilitator must be female, must understand the language of clients, and must be an experienced professional in health education, disease prevention, and risk reduction. SEPA facilitators should be certified as HIV instructors or counselors and should have received training in domestic and sexual violence. All facilitators in agencies funded by the CDC must attend the official SEPA training sponsored by the CDC before the intervention can be implemented with clients.

A minimum of .20 FTE (full-time equivalent staff) is needed for the facilitator — in other words, at least 20 percent or one-fifth of a staff person's time should be devoted to delivering SEPA. This means that the facilitator would spend about one complete eight-hour work day during a five-day work week



on SEPA, and it assumes the facilitator will have staff support for client recruitment. With .20 FTE, we estimate that approximately 60 high-risk Latinas can complete SEPA each year after year 1 which requires time for pre-implementation activities. This estimate is based on the following assumptions:

- An average of eight women completes each cycle of SEPA (a cycle consists of the six sessions in the intervention).
- There is one session each week (6 weeks to complete a cycle) and no more than one week between cycles.
- Eight cycles are completed during each 12-month period after year 1.

For about 100 high-risk women to complete SEPA each year, 12 - 13 cycles should take place. This means that two cycles will need to run concurrently nine months of the year after year 1. Staffing at the .20 FTE level should be sufficient for serving 100 clients each year because the facilitator will have gained experience conducting the intervention; thus, less time for preparation will be needed after a few cycles have taken place.

Although we suggest that one facilitator conduct each of the six sessions in a cycle to establish rapport with clients, you may want to have two women trained as facilitators. With two trained facilitators, one can serve as a substitute if needed and cycles can run concurrently to serve more clients.

Below is a list of suggested staff positions.



Suggested Minimum Staffing for SEPA⁸

STAFF POSITION	SUGGESTED NUMBER OF FTEs	COMMENTS
Facilitator	.20	Qualifications must match core element #5.
Prevention program manager	.10	This individual is responsible for supervising the facilitator and overall planning for the intervention.
Outreach/recruitment staff	.40	These staff are responsible for client recruitment and ensuring clients meet eligibility criteria.
Monitoring and evaluation staff; quality assurance staff	.20	Staff (including data-entry staff) are responsible for writing monitoring and evaluation and quality assurance plans. They are also responsible for collecting data for SMART process and outcome objectives and process evaluation and for writing monitoring and evaluation reports. Staff are also responsible for quality assurance activities and writing quality assurance reports.
Administrative and clerical support	.10	These staff assist with logistical arrangements and administrative tasks.
Childcare staff	If you decide to provide childcare during SEPA, you may want to use contractual support; also consider qualified volunteers	Check local policies, rules, and regulations before contracting with or hiring personnel to provide on-site care for babies and young children of participants.

⁸ This budget reflects minimum staffing; if there are two facilitators, the FTE percentage for facilitator should be increased.

Annual Budget



Obtaining and maintaining funding is typically the role of managerial staff. Funding can be obtained through donations, grant awards, cooperative agreements, and contracts.

- **Donations:** Monies are raised through fundraising efforts and assistance from the agency's board of directors.
- **Grants, contracts, and cooperative agreement awards:** The agency receives funding from such sources as the CDC and the state health department.

When applying for funding via a grant, contract, or cooperative agreement, budgets are written to estimate the amount of money needed to support the intervention. Budgets should be realistic and based on the agency's needs and resources. Consider the sample budget below. It contains the categories typically used by federal agencies. The dollar amounts do not suggest salary levels for your staff; they provide an example for writing a budget for SEPA. Following this sample budget is a budget worksheet to help you with calculating your estimated budget.



Sample Annual Budget for SEPA⁹

1. Personnel

Intervention Facilitator	.20 FTE x \$40,000	\$ 8,000
Program Manager	.10 FTE x \$60,000	\$ 6,000
Outreach Workers/ Recruiters	.40 FTE x \$25,000	\$ 10,000
M&E and QA staff	.20 FTE x \$50,000	\$ 10,000
Clerical Support	.10 FTE x \$22,000	\$ 2,200
	Total FTEs: 1.0	
Total Personnel		\$36,200

2. Fringe Benefits (25.06 percent)

FICA	7.65% x \$36,200	\$ 2,769
State unemployment insurance	2.79% x \$36,200	\$ 1,010
Workers Compensation	.92% x \$36,200	\$ 333
Health insurance	8.70% x \$36,200	\$ 3,149
Retirement	5.00% x \$36,200	\$ 1,810
Total Fringe Benefits		\$ 9,071

3. Travel

4 day training: 3 staff (2 facilitators, 1 program manager)	3 x \$1,500	\$ 4,500
A national HIV prevention conference 2 staff (facilitator, program manager) for four days	2 x \$1,500	\$ 3,000
Local travel (55 cents/mi. x 400 mi.)		\$ 220
Total Travel		\$ 7,720

⁹ Equipment costs will probably not be needed in subsequent annual budgets.

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4. Equipment

TV (1 wide screen)	\$ 1,200
DVD player (1)	\$ 100
Lap top computer (1)	\$ 800
LCD projector (1)	\$ 700
Screen (1)	\$ 600

Total Equipment **\$3,400**

5. Supplies

Penis models @ \$10/model x 100 (To demonstrate how to use the female condom, use a glass bottle or jar)	\$ 1,000
Male and female condoms:	
Male condoms @ \$100/1,000 condoms pack	\$ 100
Female condoms @ \$50/18 condoms x 6	\$ 300
Office supplies (e.g., easel paper, name tags, pens, pencils)	\$ 1,000
Postage	\$ 500

Total Supplies **\$ 2,900**

6. Consultants

Registered Nurse for clinical supervision @ \$50/hr. x 20 hrs You may want a registered nurse to meet with facilitators on anatomy and STD issues	\$ 1,000
Child care provider @ \$20/hr. x 96 hrs.	\$ 1,920

Total Consultants **\$ 2,920**

7. Construction

Not Applicable

8. Other

Telephone/internet/fax	\$ 1,000
Printing (e.g., ads for recruitment, flyers)	\$ 3,000
Incentives	\$ 5,000

Total Other **\$ 9,000**

Total Direct Charges (sum of 1-8)	\$71,211
Indirect Charge 18% x \$71,211	\$12,818

TOTAL YEAR 1 SAMPLE BUDGET **\$84,029**



Budget Worksheet

1. Personnel

Intervention Facilitator	<input type="text"/>	FTE x \$	<input type="text"/>	\$
Program Manager	<input type="text"/>	FTE x \$	<input type="text"/>	\$
Outreach Workers/ Recruiters	<input type="text"/>	FTE x \$	<input type="text"/>	\$
M&E and QA staff	<input type="text"/>	FTE x \$	<input type="text"/>	\$
Clerical Support	<input type="text"/>	FTE x \$	<input type="text"/>	\$

Total FTEs:

Total Personnel \$

2. Fringe Benefits (percent)

FICA	<input type="text"/>	% x \$	<input type="text"/>	\$
State unemployment insurance	<input type="text"/>	% x \$	<input type="text"/>	\$
Workers Compensation	<input type="text"/>	% x \$	<input type="text"/>	\$
Health insurance	<input type="text"/>	% x \$	<input type="text"/>	\$
Retirement	<input type="text"/>	% x \$	<input type="text"/>	\$

Total Fringe Benefits \$

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3. Travel

4 day training:		
3 staff (facilitators, program manager)	3 x \$ <input type="text"/>	\$
National HIV prevention Conference		
2 staff (facilitator, program manager)	2 x \$ <input type="text"/>	\$
for four days		
Local travel (cents/mi. x mi.)		\$
<hr/>		
Total Travel		\$

4. Equipment

TV (1 wide screen)		\$
DVD player (1)		\$
Lap top computer (1)		\$
LCD projector (1)		\$
Screen (1)		\$
<hr/>		
Total Equipment		\$

5. Supplies

Penis models		\$
Male and female condoms:		
Male condoms		\$
Female condoms		\$
Office supplies (e.g., flip charts, name tags, pens, pencils)		\$
Postage		\$
<hr/>		
Total Supplies		\$

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6. Consultants

Registered Nurse for clinical supervision

@ \$ /hour x hours* \$

[*To calculate total hours: hrs/week x # of weeks]

Total Consultants \$

7. Construction

Not Applicable

8. Other

Telephone/internet/fax \$

Printing (ads for recruitment, flyers, etc.) \$

Incentives \$

Total Other \$

Total Direct Charges (sum of 1-8) \$

Indirect Charge \$

TOTAL YEAR 1 BUDGET \$

Location for Delivering SEPA



Community-based organizations may choose to conduct SEPA at their offices or at other facilities that are accessible to clients, such as healthcare clinics and other agencies or centers that serve the Latino community.

Select a room that will comfortably accommodate up to 14 individuals: 12 participants, the facilitator, and a volunteer assistant. To maintain privacy, use a room with a door that can be closed. Arrange comfortable chairs around a table positioned into a U-shape. The room should be large enough to include this U-shape table plus a table for the computer/LCD projector, a table in the back of the room for refreshments and handout materials, a screen, and an easel. The room should also be large enough for clients to rearrange their chairs to face a partner during practice exercises and role plays. Keep the room at a comfortable temperature.

Client Recruitment and Retention

As discussed previously, the target population consists of Latinas between the ages of 18 and 44 who are at risk of acquiring HIV due to unprotected vaginal and anal intercourse. Participants should be able to understand and read English. When recruiting participants, make sure they meet at least one of the following criteria:

1. Within the six months prior to the start of the intervention, potential client has engaged in at least one episode of unprotected vaginal or anal intercourse with a male sex partner of unknown HIV serostatus, or with a male sex partner who is living with HIV.



2. Within the six months prior to the start of the intervention, potential client has received treatment for at least one sexually transmitted disease.

Client recruitment and retention pose great challenges to community-based organizations funded to deliver evidence-based HIV prevention programs. Recruitment usually includes identifying members of the target population who are at risk for either transmitting or acquiring HIV. SEPA is for women who are not infected with HIV and therefore are at risk for acquiring the virus; their risk stems from unprotected sex. If recruitment/outreach staff are responsible for screening clients for HIV risk according to the criteria discussed above, they must know and understand the reasoning behind the eligibility criteria and they must be trained to solicit information about sexual risk behaviors. It is also beneficial for outreach workers to know how social networking techniques can help with recruitment. A source of information on social networking for recruiting persons into HIV testing programs is <http://www.cdc.gov/hiv/resources/guidelines/snt/index.htm>. In addition to recruitment for testing, social networking strategies can also be used to recruit clients for behavior change interventions.

Some community-based organizations have been successful using peer outreach workers for recruitment. CDC suggests that at least two persons conduct recruitment as a team and that there is one supervisor for every 10 outreach workers.

Because client recruitment and retention are essential activities, agencies funded to implement SEPA must prepare a client recruitment and retention plan before the intervention is conducted with clients. The purpose of the plan is to provide written information for recruitment staff, facilitators, and other agency staff so that SEPA sessions can average about 10 participants who

meet the intervention's eligibility criteria. The ideal size for a group is 12 participants.

The recruitment and retention plan should be informed by substantive knowledge of how to reach the target population in person and by various types of media, as well as knowledge of how to engage clients in small group-level interventions. Members of the target population or a client advisory committee as well as former clients, intervention staff, and members of your board of directors can help with development of the plan. When creating your agency's recruitment and retention plan for SEPA, review the problem statement in SEPA's behavior change logic model and note the risk behaviors and risk factors.

Client Recruitment



Methods for recruiting clients include posting flyers at recruitment venues, publishing ads in Latino newspapers and magazines, developing public service announcements for local Latino radio and TV stations, providing information on Web sites popular with Latinos, and writing memoranda of agreement with other agencies that serve Latinas so these agencies can make appropriate referrals to SEPA. See the sample marketing and recruitment flyer (Appendix C) as a reference for your marketing documents.

Your plan's discussion about recruitment should cover:

- Procedures for referring agency clients to SEPA (you need to make sure all intervention staff and all staff who have contact with clients know about the intervention)
- Wording for written materials, such as brochures, flyers, and posters, to advertise the intervention
- Locations where written materials should be distributed



- Media that can be used to advertise the intervention, such as print media (Latino newspapers and magazines), radio, and television
- Direct mailings to members of the target population
- Web sites popular with Latinas where information about SEPA can be placed
- Strategies for approaching potential participants and language for describing SEPA
- Places and locations frequented by potential participants
- Agencies that provide services to the target population that can post materials and whose staff can refer clients to SEPA such as agencies that provide HIV counseling and testing, health care and STD clinics, and agencies that provide prevention programs for persons living with HIV. You may want to write memoranda of agreement with these agencies to facilitate referrals from them

Outreach workers should visit locations where the target population can be found to speak directly with them and to distribute promotional materials. Examples of venues at which to launch recruitment efforts include:

- Low-income and working class Latino neighborhoods
- Community health clinics in Latino neighborhoods
- STD clinics in Latino neighborhoods
- Offices of doctors that serve the Latino community
- Service agencies that Latinas use, such as planned parenthood, GED programs, ESL programs, subsidized housing developments, and Head Start sites
- Bars, clubs, coffee shops, and restaurants frequented by Latinas
- Grocery stores, laundromats, beauty shops, community centers, and child care centers in the Latino community or specific areas of one or more Latino communities
- Street and/or park locations where Latinas congregate
- Churches attended by Latinos

- Shopping malls popular with Latinos
- Latino community meetings

To identify additional venues, consider conducting focus groups with potential clients or current and former clients. Current and past participants are natural recruiters because they are familiar with the agency and your programs and may have great ideas on how and where to recruit clients. Remember to ask women who completed SEPA to refer at least one friend.



Client Retention

Discussion of client retention is the second part of your plan. The behavior change objectives of SEPA will never be met if participants are unwilling to stay past the first session and if they are not actively engaged in discussions and activities. Strategies to retain clients include:

- Providing incentives, such as gift cards, public transportation passes, toiletries and cosmetics, children's gifts, and discount coupons for restaurants
- Making reminder calls or sending reminder e-mails after each session
- Assisting with or providing transportation to and from sessions
- Providing refreshments or meals before or after sessions so participants can socialize
- Providing or paying for childcare

One way to maximize retention is to make sure SEPA is conducted at an accessible location and at convenient times for clients. Another suggestion is



to ensure that SEPA is facilitated by competent staff who establish relationships of trust and caring with clients. Facilitators should understand the context for clients' HIV risk behaviors and how cultural and gender-specific values affect those behaviors. When facilitators know how to engage clients in discussion and how to motivate them to actively participate in activities, client retention problems will be reduced. Another suggestion is for facilitators to celebrate the accomplishments of clients who consistently do homework and actively participate in sessions with small gifts or notes of congratulations. Note that core element #6 indicates that clients who attend at least half of the sessions should receive a certificate during the last session.

Throughout its six sessions, SEPA emphasizes the importance of sharing information on safer sex and healthy behaviors with friends, family, and members of the community. When facilitators communicate this message in a sincere way and with a sense of urgency, clients may be more inclined to attend all sessions of the intervention.

Community Advisory Board

If you do not already have one, we suggest you establish a community advisory board or committee to provide guidance on pre-implementation activities. The committee serves as a liaison between the agency and clients and should be composed of approximately 10 members of the target population. These individuals can help with development of your client recruitment and retention plan and with the actual recruitment. They can also assist with the adaptation activities discussed below, provide advice to staff for improving implementation, and help ensure that participants' rights are protected.



Program Review Panels

Before SEPA can be implemented with clients, each agency funded by the CDC must have all SEPA materials approved by its Program Review Panel. The role of the review panel is to ensure that materials are appropriate for the intended population, that they do not promote or encourage sexual activity and intravenous substance abuse, and that they are not obscene. You are responsible for providing proof of review and approval status of materials when requested by the CDC. Information on program review panels is available at <http://www.cdc.gov/od/pgo/forms/hiv.htm>.

Agency Readiness



You are ready to implement SEPA with clients when the following actions have been accomplished:

- A facilitator has been identified or hired and trained
- Additional intervention staff have been identified or hired and trained
- All intervention staff have read the Implementation Manual
- All equipment, materials, and supplies have been secured; equipment is in good working order
- The location, dates, and times for conducting SEPA have been determined
- The following documents have been written and reviewed with staff:
 - Client recruitment and retention plan with screening criteria and discussion of use of client incentives
 - Monitoring and evaluation plan
 - Quality assurance plan
 - Agency policies on such topics as making and tracking client referrals and client confidentiality
- There are between 10 and 12 eligible clients who are enrolled for the first cycle of the intervention, and eligible clients have been identified for the second cycle

The checklist on the following page is a tool to help determine if you are ready to implement SEPA.



Agency Readiness Checklist

REQUIRED ACTION	YES Ready to implement	NO Not ready to implement
Facilitator hired and trained		
All intervention staff in place		
All intervention staff have read Implementation Manual		
All equipment and supplies are in place		
Locations, dates, and times for implementation have been determined		
Recruitment and retention plan, M&E plan, and QA plan have been reviewed with staff		
Agency policies have been written and reviewed with staff		
There are between 10 and 12 eligible clients enrolled for the first cycle and eligible clients have been identified for the second cycle		



Pre-Implementation Timeline

As we have emphasized, it requires preparation time to be ready to serve clients. The following are some of the activities that must take place during your first year of funding before the first session of SEPA is conducted: hiring staff; training facilitators; and writing client recruitment and retention, monitoring and evaluation, and quality assurance plans. A suggested timeline to help agencies with planning and implementation is included below.

Suggested Pre-Implementation Timeline for SEPA*

Task	Staff Assigned	Timeline
Inform agency staff about SEPA	Project manager/ supervisor	Within first month of the program year
Inform community or client advisory board about SEPA	Project manager/ supervisor	Within first month of the program year
Inform agency board of directors about SEPA	Project manager/ supervisor or executive director	Within first month of the program year
Agencies directly funded by CDC: Inform health department and community planning group about SEPA	Project manager/ supervisor or executive director	Within first month of the program year
Identify/hire SEPA facilitator	Project manager/ supervisor	Within first two months of the program year
Secure CDC SEPA training for facilitator	Project manager/ supervisor	Within first three months of the program year
Identify/hire other staff for SEPA as needed, such as recruiters, monitoring and evaluation and quality assurance personnel, and administrative support	Project manager/ supervisor	Within first two months of the program year

* According to this timeline, SEPA will start by the seventh month of the first program year. While recognizing that various factors affect the start date, the project should begin no later than the eighth month of the first program year.

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Task	Staff Assigned	Timeline
Based on budget, determine how many cycles of SEPA to conduct during the program year; determine dates and times for the cycles	Project manager/ supervisor	Within first two months of the program year
Develop client screening criteria and write client recruitment and retention plan (see discussion in this manual)	Project manager/ supervisor and/or SEPA facilitator	Within first three months of the program year
Obtain Program Review Panel approval for SEPA materials	Project manager/ supervisor and/or SEPA facilitator	Within first three months of the program year
Meet with and provide written information on Project SEPA to agencies to which clients may be referred, and write memoranda of understanding with these agencies	Project manager/ supervisor and/or SEPA facilitator	Within first three months of the program year
Meet with and provide written information on SEPA to agencies that serve members of the target population and that may assist with client recruitment	Project manager/ supervisor and/or SEPA facilitator	Within first three months of the program year
Write monitoring and evaluation (M&E) and quality assurance (QA) plans	Project manager/ supervisor and/or SEPA facilitator and/or program evaluator/quality assurance staff	Within first four months of the program year
Write needed agency policies and procedures, such as procedure for making and tracking referrals and policy on client confidentiality	Project manager/ supervisor or executive director	Within first four months of the program year
Secure needed materials, equipment, and supplies (see list in this Implementation Manual)	Project manager/ supervisor and/or SEPA facilitator	Within first four months of the program year
Identify and/or secure venue/location for SEPA sessions (see discussion of location in this Implementation Manual)	Project manager/ supervisor and/or SEPA facilitator	Within first four months of the program year

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Task	Staff Assigned	Timeline
Begin recruitment of clients	Outreach or other assigned staff	Begin during month four and continue through the end of the first year and in accordance with client recruitment and retention plan
Implement SEPA	SEPA facilitator	Begin by month seven and continue through the end of the program year
Collect data in accordance with monitoring and evaluation plan	SEPA facilitator and/or program evaluator	From beginning to end of program year
Carry out quality assurance processes in accordance with quality assurance plan	Project manager/supervisor, SEPA facilitator, and quality assurance staff	From beginning to end of program year
Prepare monitoring and evaluation and quality assurance reports in accordance with M&E and QA plans	Program evaluator/quality assurance staff	In accordance with M&E and QA plans

Agencies may frame first-year planning and preparation activities as SMART objectives — objectives that are specific, measurable, appropriate, realistic, and time-based. For example, using the first task in the suggested timeline, a SMART objective could read, “No later than the end of the first month of the first program year, the prevention project manager will meet with all prevention program staff, including administrative personnel, to discuss SEPA, noting the target population, session topics, and key intervention activities. The prevention program manager also will distribute copies of the SEPA fact sheet and behavior change logic model to all staff.”

Adaptation



Adaptation is the process of modifying an evidence-based intervention while maintaining fidelity to the intervention’s core elements. There are two main reasons for an agency to adapt an evidence-based intervention: (1) to meet the prevention needs of a specific population for whom evidence-based interventions are lacking, and (2) to address agency infrastructure and resource constraints. The intervention’s key characteristics, not the intervention’s core elements, can be modified to meet target population and agency needs. Core elements must be maintained because they contribute to the intervention’s success in achieving outcome objectives, including the safer sex behavior changes you want clients to achieve.

Decisions about adaptation and actual adaptation activities, such as making revisions to the intervention’s curriculum, should include agency staff and a community advisory board composed of members of the specific population you want to reach. The reasons for adaptation and all processes used to modify the original evidence-based intervention should be put into writing. If your agency is funded by the CDC’s Division of HIV/AIDS Prevention, you must include your project officer in discussions about adaptation and share written materials with that individual. Your project officer can discuss capacity-building assistance available from the CDC at <http://www.cdc.gov/hiv/cba>. If you are “indirectly” funded by CDC through your health department, check with health department staff to request assistance on adaptation.

Recognize that attitudes about sexual behavior and male and female relationships are influenced by cultural values. Know the culture of the clients you want to serve and use this knowledge if you decide to adapt SEPA for a new population.



To determine whether SEPA can be adapted to meet the needs of a different population and/or to meet agency needs, the agency and members of the community advisory board should review SEPA's behavior change logic model, its core elements, and its key characteristics. The discussion that follows explains how these materials can be used to inform adaptation decisions.

Serve a Different Population

Although SEPA was designed to meet the HIV prevention needs of Hispanic/Latina women with a specific risk profile, its core elements can be maintained if the target population includes women who are not Hispanic or Latina. This means that SEPA can be adapted for African American, American Indian, Alaska Native, Asian, Black, Native Hawaiian, other Pacific Islander, or White women **if** their prevention needs and determinants of behavior change are congruent with SEPA's behavior change logic model.

The logic model's problem statement reads:

“Hispanic women/Latinas between the ages of 18 and 44 are at risk for HIV and STD infection when they have unprotected sex with male partners. Explanations for unprotected sex include lack of knowledge about sexually transmitted diseases, including HIV; negative attitudes toward condoms; a shortage of effective communication skills; reluctance to discuss condoms due to fear of violence from male partners; the absence of skills to negotiate condom use and to use male and female condoms correctly; and low risk-reduction behavioral intentions. Research suggests that social and cultural factors, such as gender inequality and gender role socialization, including Machismo and Marianismo, are associated with insufficient knowledge about HIV and STD transmission and prevention and inadequate ability to communicate effectively with male partners. These factors are likely sources of disempowerment that contribute to HIV risk among Hispanic women/Latinas.”

If the population in need of HIV prevention consists of women whose primary risk behavior is unprotected vaginal or anal sex with males, and explanations for this behavior include insufficient knowledge about HIV and STDs, negative attitudes toward condom use, inadequate communication skills, fear of violence from male partners, lack of condom use and condom-negotiation skills, and low risk-reduction behavioral intentions, then SEPA may be an appropriate intervention to consider adapting for your target population.



The logic model's determinants of behavior change must apply to your population's HIV prevention needs. If the problem statement fits the population (excluding references to Latino culture), then it is likely that the determinants also will be a good fit. For SEPA clients, the determinants of behavior change are knowledge, attitudes, self-efficacy, and intentions, and the intervention's activities are designed to address these determinants so that the immediate and intermediate outcomes identified in the logic model can be achieved.

SEPA's activities include presentations, discussions, and skill-building activities to increase knowledge of HIV and STDs; to enhance self-efficacy for condom use, condom negotiation, and effective communication; to foster favorable attitudes toward condoms; and to increase intentions for safer sex behaviors. Session content covers HIV and STD transmission and prevention, male and female reproductive anatomy, human sexuality, interpersonal communications, and domestic and intimate partner violence. Skill-building and practice exercises focus on male and female condom use, condom negotiation, and assertive communication.



These activities are designed to affect the determinants of behavior change identified in the logic model and they promote the intervention's expected outcomes. Immediate outcomes are increases in HIV knowledge, favorable attitudes toward condom use; self-efficacy for partner communication skills, condom use skills, and condom-negotiation skills; and increases in risk-reduction behavioral intentions. The intermediate outcome is an increase in correct and consistent condom use with sex partners.

If you believe that SEPA's activities are the activities needed to reduce HIV risk behavior among members of the population you want to serve, and if the outcomes listed in SEPA's behavior change logic model are the outcomes you want the population to achieve, then SEPA is an appropriate intervention to consider for adaptation. It's a good idea to develop a new behavior change logic model to make sure the relationships among determinants, activities, and outcomes are appropriate for the target population. If SEPA does not meet the prevention needs of the "new" target population, you should select another intervention more suitable for the population.

Modify the Curriculum to Make it Appropriate for the Target Population

If you have decided that SEPA is appropriate for a population of women who are not Hispanic or Latina, the next step is to review the curriculum found in the Facilitators Guide. It is important to review the curriculum and written materials given to participants for cultural and linguistic compatibility with the target population. The curriculum indicates how presentations, discussions, and skill-building activities are communicated to participants. The curriculum contains the content for information and discussion topics and instructions for activities. You and your client advisory committee should carefully review the language used to convey information and instructions and to prompt discussion, as well as the graphics and images on materials distributed to participants, with an eye toward modifications needed to provide an appropriate and relevant cultural context.



Modifications to the SEPA curriculum cannot change the core elements of the intervention. The following core elements apply to the curriculum or the content of the intervention.

- Provide culturally and linguistically appropriate information to sexually active women at risk of acquiring HIV from unprotected sex with male partners in interactive, small-group sessions that focus on:
 - a. HIV and STD transmission and prevention
 - b. Human sexuality and male and female anatomy
 - c. Interpersonal communications
 - d. Relationship violence
- Incorporate skill-building activities into sessions to enhance women's self-efficacy for safer sex behaviors, including demonstrations and practice exercises on male and female condom use and role-plays on assertive communication with sex partners, such as condom negotiation.
- Build self-efficacy and knowledge for safer sex behaviors, improved communication with partners, and violence management through homework exercises and the sharing of personal experiences.
- Show a culturally appropriate video during the first session that portrays the effects of HIV and AIDS on members of the target population, and discuss what is communicated about the impact of HIV and AIDS on the community, including impacts on families and women.
- Ask participants to write thank-you notes to fellow participants and pledge their commitment to community health during the final session. Present a certificate to each participant who attends at least half of the sessions.

Review of these core elements reveals that changes may not be made to the content contained in the six sessions of the intervention. None of the content can be eliminated. The wording used to communicate the content can be modified for cultural congruence, but the content itself — including discussion topics, skill-building activities, homework assignments, and activities during Session 6 — should not be changed.

There is flexibility in the choice of a video to show during Session 1. The video for Hispanic/Latina women is “Mi Hermano.” You will need to use a different video for a different target population and you will need to revise the discussion questions and references to the Latino community in the current curriculum.

Other changes that need to be made to accommodate a different population for SEPA are as follows:



- Change the name of the intervention.
- Change the HIV and AIDS surveillance data presented in Session 1.
- Modify the list of celebrities for the collage on persons infected with HIV used in Session 1.
- Change the names in “The Story of Juanita” in Session 2.

The Participant Workbook should also be reviewed for needed changes.

Serve Older Latinas

The target ages of 18 through 44 were selected because this was the age group of the women who participated in the original research on the intervention. However, the information provided by SEPA is relevant to women older than 44 who are at risk for HIV infection due to unprotected sex. If you decide to target an older group of Latinas with the HIV prevention needs identified in SEPA’s behavior change logic model, follow the process described above on adapting SEPA for a different target population. This



means you need to work with a community advisory board composed of Latinas older than 44, and all materials should be reviewed to make sure they are appropriate for older women. Changes to materials must preserve all core elements of the intervention.

If you want SEPA groups to consist of a mix of ages, such as 25 to 55, it is best to conduct a pilot test of the six sessions to assess group participation and interaction before you continue with subsequent groups. As noted, SEPA calls for active client engagement in discussions and activities. If younger and older women are reluctant to share experiences and fully engage in discussions and activities, then additional groups of mixed ages should not be scheduled.

Adaptation for Agency Needs

At times, agencies want to adapt an evidence-based intervention because their infrastructure and resources may not be adequate to support the intervention. For example, an agency may not have the physical space needed to conduct the intervention, or staff with required experience and training may not be available. There is a core element of SEPA that addresses qualifications of the person who conducts the intervention, known as the facilitator. This core element reads:

Use a female facilitator who speaks and understands the language of participants. The facilitator is not a peer of participants but someone who is an experienced professional in health education, disease prevention, and risk reduction.

This means that the facilitator must be a woman who is linguistically competent to conduct the intervention with the specific target population. For example, if an agency in Los Angeles wants to adapt SEPA for Filipino women/Filipinas, the facilitator should be conversant in Tagalog. In addition, she must be an experienced professional in a health-related field.

There are two key characteristics that relate to staffing:



1. Employ facilitators who are certified by the American Red Cross as HIV instructors or who have attended HIV prevention training sponsored by a health department or prevention training center. Employ facilitators who have received training in domestic violence and sexual violence.
2. Invite a former SEPA participant who completed all sessions to assist with such activities as room setup and the distribution of handout materials.

The first key characteristic conveys what training is desirable for SEPA facilitators in addition to the basic training on the intervention. Although HIV prevention, domestic violence, and sexual violence training are desired, there is no requirement for facilitators to receive this training. Likewise, there is no requirement for former participants to assist current facilitators with logistical tasks.

Although there is no core element that addresses the location or physical space where SEPA should take place, sessions should be held where women can speak confidentially and feel safe.

There is a core element that notes how often SEPA sessions should be held. No more than two sessions are to take place each week because participants need time to complete homework assignments, which entail practicing skills and sharing information learned during the intervention. This means that SEPA cannot take place during a weekend retreat or over consecutive days.

The final key characteristic that relates to agency resources reads: "Provide transportation assistance and childcare services to participants. Provide light refreshments at each session." Some agencies may not have the financial resources to provide assistance with transportation and childcare; some may not be able to afford refreshments for participants.



Modify Recruitment Strategies

Although there is no core element or key characteristic that directly addresses recruitment, information regarding recruitment and retention discussed earlier should be reviewed and modified so that recruitment strategies are appropriate for the new target population. Your recruitment and retention plan will need to be revised to reflect changes in recruitment venues, messages, and approaches.

What Should Be Done After Needed Modifications Are Identified?

After agency staff and members of the community advisory board (composed of women from the new target population) determine needed modifications to the curriculum/Facilitators Guide and the Participant Workbook, and after selecting a new video, revised documents need to be prepared. In addition to the Facilitators Guide and Participant Workbook, revisions may need to be made to sections of the Implementation Manual.

After all revisions have been made to accommodate a new population, the intervention should be pilot tested in its entirety with eight to 10 members of the target population.¹⁰ Use the evaluation worksheets in the Participant Workbook during the pilot to assess the intervention's acceptability, relevance, and usefulness. Staff and a few members of the advisory board should observe all six sessions and discuss their recommendations to improve cultural and linguistic competence and overall acceptability by the target population.

After review by your CDC project officer, or another funder, final revisions can be made to intervention materials to complete the adaptation process. If a facilitator needs to be hired, she must become thoroughly familiar with all intervention materials before the first session takes place with the new population.

¹⁰ If an appropriate facilitator has not been hired to conduct the pilot, a female staff member with group facilitation skills should serve as facilitator.



A summary of the key steps in adaptation for a “new” target population appears below.

Summary of Key Adaptation Steps

Work with a community advisory board composed of members of the “new” population to:

1. Review SEPA’s behavior change logic model and its core elements and key characteristics.
2. Determine whether the problem statement and the logic model’s determinants of behavior change apply to the “new” population’s HIV prevention needs.
3. Determine whether the outcomes identified in the behavior change logic model are the outcomes you want the “new” population to achieve.

If you answer yes to steps 2 and 3, then the intervention fits your target population; continue to step 4

4. Review the curriculum found in the Facilitators Guide, as well as written materials given to participants, for cultural and linguistic compatibility with the “new” target population.

Modifications to the SEPA curriculum cannot change the core elements of the intervention.

5. Determine needed modifications to the curriculum/Facilitators Guide, the Participant Workbook, and the Implementation Manual.
6. Revise materials as needed.



7. Pilot test the intervention, using the revised materials, with eight to 10 members of the “new” target population. Use client feedback forms to assess acceptability by the “new” population.
8. Revise materials as needed.
9. Submit revised materials and summaries of client and staff feedback to your CDC or other project officer for review.
10. Incorporate the project officer’s comments into materials to complete the adaptation process.



Ongoing Implementation Activities

Thorough discussion of implementation is found in the Facilitators Guide which provides a scripted curriculum for each of SEPA’s six sessions. This timeline provides an overview of major implementation activities that should take place over the entire project period. Activities involve the facilitator and other staff such as your prevention supervisor, recruitment staff, and monitoring and evaluation and quality assurance staff.

ACTIVITY	WHEN ACTIVITY SHOULD TAKE PLACE
Telephone and/or email participants to remind them of the session	Before each session of the intervention
Check that all materials, equipment, and supplies are available and in good working order	Before each session of the intervention
Make sure refreshments are available if you supply them to participants	Before each session of the intervention
If on-site child care services are made available for participants, remind providers of the location and times for each session	Before each cycle of the intervention
Meet with supervisor to discuss issues, concerns, successes, and implementation with fidelity to core elements	At least once a month
Check that there are at least 12 eligible women for the upcoming cycle	Before each scheduled cycle of SEPA
Review handout materials to see if updated materials are available	At least twice a year
Meet with program monitoring and evaluation staff and quality assurance staff to review data collection tools and checklists used to monitor fidelity to core elements	At least twice a year
Meet with supervisor and monitoring and evaluation and quality assurance staff to review reports and discuss ways to improve implementation	At least twice a year



CONCLUSION

We hope the information in this starter kit has helped inform agency decision-making on intervention selection and adaptation. With proper planning and pre-implementation activities, agencies funded to conduct SEPA will be in an excellent position to reap the HIV prevention rewards of those efforts. For more information on SEPA and CDC training and technical assistance for SEPA, please visit www.effectiveinterventions.org.



APPENDIX A

Sample SEPA General Information Flyer



WHAT IS SEPA?

SEPA is an evidence-based HIV prevention intervention for Hispanic women/Latinas at risk of HIV infection due to unprotected sex with male partners.

WHAT IS THE EVIDENCE BASIS OF SEPA?

Based on Social Cognitive Theory, **SEPA** produced significant outcomes among low-income Mexican and Puerto Rican women between the ages of 18 and 44 in Chicago where the intervention was tested. Compared to members of the control group, **SEPA** participants showed significant increases in:

- HIV knowledge
- Communication with partners about HIV issues
- Risk-reduction behavioral intentions
- Condom use

In addition, **SEPA** participants had significant decreases in perceived barriers to condom use.

WHO IS THE AUDIENCE FOR SEPA?

SEPA was developed to educate Hispanic women/Latinas between the ages of 18 and 44 about HIV and other STDs and to help them build the skills necessary for behavioral changes that lead to more healthy relationships and safer sex.

Although the intervention's efficacy trial included Mexican and Puerto Rican women, researchers believe **SEPA** can be of benefit to at-risk women of diverse races and ethnicity if their prevention needs can be addressed by **SEPA**'s activities.

"Everyone needs a strong sense of self. It is our base of operations for everything that we do in life."

Julia T. Alvarez
Writer, Poet, and Diplomat

WHAT HAPPENS DURING SEPA?

SEPA consists of six two-hour sessions that include presentations, group discussions, and practice exercises on male and female condom use, condom negotiation, and assertive communication. Session content covers HIV and STD transmission and prevention, male and female reproductive anatomy, human sexuality, interpersonal communications, and domestic and intimate partner violence.

"I change myself, I change the world."

Gloria Anzaldua
Writer and Poet

WHO SHOULD IMPLEMENT SEPA?

Agencies that serve the Latino community should employ a female facilitator who speaks and understands the language of participants to implement **SEPA**. The facilitator is not a peer of participants but someone who is an experienced professional in health education, disease prevention, and risk reduction.

WHAT ARE THE BENEFITS OF SEPA?

Agencies, clients, and the Latino community can all benefit from **SEPA**. By implementing **SEPA**, agencies know they provide HIV prevention that works to reduce risky sexual behavior. Clients benefit because they learn how to protect their health and improve relationships with partners. When women in the community are healthy and there are reduced rates of HIV and STDs, the entire Latino community benefits.

"Deserve your dream."

Octavio Paz
Writer, Poet, and Diplomat

For more information on **SEPA**, contact:



APPENDIX B

Sample SEPA Recruitment and Marketing Flyer



Join Fellow Latinas for Weekly Discussions of How to Help Yourself, Your Family, and the Community

Learn about important health issues and ways to improve your relationship with your husbands or boyfriends and with family and friends.

For information on Latina discussion groups call or email:

Name/Agency
Email address
Phone number

Do you know that:

- HIV/AIDS was the fourth leading cause of death among Hispanic/Latino men and women between the ages of 35 and 44 in 2005?
- There's a way to communicate with other people that makes it easier to talk about your thoughts and feelings?
- Some men and women have sexually transmitted diseases and don't even know it?
- Over a million women in the United States are assaulted by intimate partners each year?
- There's a law called the Violence against Women Act that can help undocumented women who are the victims of domestic violence?



**LEARN MORE INTERESTING AND HELPFUL
INFORMATION AT OUR WEEKLY DISCUSSION
GROUPS FOR LATINAS**



APPENDIX C

CDC Required Documents

- **The ABC's of Smart Behavior**
- **Content of AIDS-Related Written Materials, Pictorials, Audiovisuals, Questionnaires, Survey Instruments, and Educational Sessions in Centers for Disease Control and Prevention (CDC) Assistance Programs**
- **Notice to Readers: CDC Statement on Study Results of Produce Containing Nonoxynol-9**
- **Nonoxynol-9 Spermicide Contraception Use---United States, 1999**
- **Fact Sheet for Public Health Personnel; Male Latex Condoms and Sexually Transmitted Diseases**



The ABCs of Smart Behavior

To avoid or reduce the risk for HIV

- **A** stands for abstinence.
- **B** stands for being faithful to a single sexual partner.
- **C** stands for using condoms consistently and correctly.



**CONTENT OF AIDS-RELATED WRITTEN MATERIALS,
PICTORIALS, AUDIOVISUALS, QUESTIONNAIRES, SURVEY
INSTRUMENTS, AND EDUCATIONAL SESSIONS IN CENTERS FOR
DISEASE CONTROL AND PREVENTION (CDC) ASSISTANCE PROGRAMS**



Interim Revisions June 1992

1. Basic Principles

Controlling the spread of HIV infection and AIDS requires the promotion of individual behaviors that eliminate or reduce the risk of acquiring and spreading the virus. Messages must be provided to the public that emphasize the ways by which individuals can fully protect themselves from acquiring the virus. These methods include abstinence from the illegal use of IV drugs and from sexual intercourse except in a mutually monogamous relationship with an uninfected partner. For those individuals who do not or cannot cease risky behavior, methods of reducing their risk of acquiring or spreading the virus must also be communicated. Such messages can be controversial. These principles are intended to provide guidance for the development and use of educational materials, and to require the establishment of Program Review Panels to consider the appropriateness of messages designed to communicate with various groups.

- a. Written materials (e.g., pamphlets, brochures, fliers), audio visual materials (e.g., motion pictures and video tapes), and pictorials (e.g., posters and similar educational materials using photographs, slides, drawings, or paintings) should use terms, descriptors, or displays necessary for the intended audience to understand dangerous behaviors and explain less risky practices concerning HIV transmission.
2. Written materials, audiovisual materials, and pictorials should be reviewed by Program Review Panels consistent with the provisions of Section 2500 (b), (c), and (d) of the Public Health Service Act, 42 U.S.C. Section 300e(b), (c), and (d), as follows:

"SEC. 2500. USE OF FUNDS.

(b) CONTENTS OF PROGRAMS. - All programs of education and information receiving funds under this title shall include information about the harmful effects of promiscuous sexual activity and intravenous substance abuse, and the benefits of abstaining from such activities.

(c) LIMITATION. - None of the funds appropriated to carry out this title may be used to provide education or information designed to promote or encourage, directly, homosexual or heterosexual sexual activity or intravenous substance abuse.

(d) CONSTRUCTION. - Subsection (c) may not be construed to restrict the ability of an education program that includes the information required in subsection (b) to provide accurate information about various means to reduce an individual's risk of exposure to, or to transmission of, the etiologic agent for acquired immune deficiency syndrome, provided that any informational materials used are not obscene."

c. Educational sessions should not include activities in which attendees participate in sexually suggestive physical contact or actual sexual practices.

d. Messages provided to young people in schools and in other settings should be guided by the principles contained in "Guidelines for Effective School Health Education to Prevent the Spread of AIDS" (MMWR 1988;37 [suppl. no. S-2]).

2. Program Review Panel

- a. Each recipient will be required to establish or identify a Program Review Panel to review and approve all written materials, pictorials, audiovisuals, questionnaires or survey instruments, and proposed educational group session activities to be used under the project plan. This requirement applies regardless of whether the applicant plans to

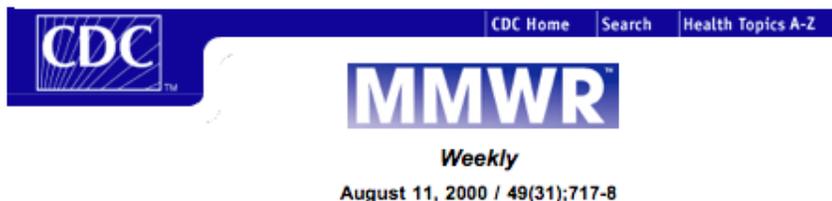
<http://www.cdc.gov/od/pgo/forms/hiv.htm>

conduct the total program activities or plans to have part of them conducted through other organization(s) and whether program activities involve creating unique materials or using/distributing modified or intact materials already developed by others. Whenever feasible, CDC funded community-based organizations are encouraged to use a Program Review Panel established by a health department or another CDC-funded organization rather than establish their own panel. The Surgeon General's Report on Acquired Immune Deficiency Syndrome (October 1986) and CDC-developed materials do not need to be reviewed by the panel unless such review is deemed appropriate by the recipient. Members of a Program Review Panel should:

- (1) Understand how HIV is and is not transmitted; and
 - (2) Understand the epidemiology and extent of the HIV/AIDS problem in the local population and the specific audiences for which materials are intended.
2. The Program Review Panel will be guided by the CDC Basic Principles (in the previous section) in conducting such reviews. The panel is authorized to review materials only and is not empowered either to evaluate the proposal as a whole or to replace any other internal review panel or procedure of the recipient organization or local governmental jurisdiction.
 3. Applicants for CDC assistance will be required to include in their applications the following:
 - (1) Identification of a panel of no less than five persons which represent a reasonable cross-section of the general population. Since Program Review Panels review materials for many intended audiences, no single intended audience shall predominate the composition of the Program Review panel, except as provided in subsection (d) below. In addition:
 - (a) Panels which review materials intended for a specific audience should draw upon the expertise of individuals who can represent cultural sensitivities and language of the intended audience either through representation on the panels or as consultants to the panels.
 - (b) The composition of Program Review Panels, except for panels reviewing materials for school-based populations, must include an employee of a State or local health department with appropriate expertise in the area under consideration who is designated by the health department to represent the department on the panel. If such an employee is not available, an individual with appropriate expertise, designated by the health department to represent the agency in this matter, must serve as a member of the panel.
 - (c) Panels which review materials for use with school-based populations should include representatives of groups such as teachers, school administrators, parents, and students.
 - (d) Panels reviewing materials intended for racial and ethnic minority populations must comply with the terms of (a), (b), and (c), above. However, membership of the Program Review Panel may be drawn predominately from such racial and ethnic populations.
 - (2) A letter or memorandum from the proposed project director, countersigned by a responsible business official, which includes:
 - (a) Concurrence with this guidance and assurance that its provisions will be observed;
 - (b) The identity of proposed members of the Program Review Panel, including their names, occupations, and any organizational affiliations that were considered in their selection for the panel.
 4. CDC-funded organizations that undertake program plans in other than school-based populations which are national, regional (multi state), or statewide in scope, or that plan to distribute materials as described above to other organizations on a national, regional, or statewide basis, must establish a single Program Review Panel to fulfill this requirement. Such national/regional/State panels must include as a member an employee of a State or local health department, or an appropriate designated representative of such department, consistent with the provisions of Section 2.c.(1). Materials reviewed by such a single (national, regional, or state) Program Review Panel do not need to be reviewed locally unless such review is deemed appropriate by the local organization planning to use or distribute the materials. Such national/regional/State organization must adopt a national/regional/statewide standard when applying Basic Principles 1.a. and 1.b.
 5. When a cooperative agreement/grant is awarded, the recipient will:

<http://www.cdc.gov/od/pgo/forms/hiv.htm>

- (1) Convene the Program Review Panel and present for its assessment copies of written materials, pictorials, and audiovisuals proposed to be used;
- (2) Provide for assessment by the Program Review Panel text, scripts, or detailed descriptions for written materials, pictorials, or audiovisuals which are under development;
- (3) Prior to expenditure of funds related to the ultimate program use of these materials, assure that its project files contain a statement(s) signed by the Program Review Panel specifying the vote for approval or disapproval for each proposed item submitted to the panel; and
- (4) Provide to CDC in regular progress reports signed statement(s) of the chairperson of the Program Review Panel specifying the vote for approval or disapproval for each proposed item that is subject to this guidance.



Notice to Readers: CDC Statement on Study Results of Product Containing Nonoxynol-9

During the XIII International AIDS Conference held in Durban, South Africa, July 9--14, 2000, researchers from the Joint United Nations Program on AIDS (UNAIDS) presented results of a study of a product, COL-1492,* which contains nonoxynol-9 (N-9) (1). N-9 products are licensed for use in the United States as spermicides and are effective in preventing pregnancy, particularly when used with a diaphragm. The study examined the use of COL-1492 as a potential candidate microbicide, or topical compound to prevent the transmission of human immunodeficiency virus (HIV) and sexually transmitted diseases (STDs). The study found that N-9 did not protect against HIV infection and may have caused more transmission. The women who used N-9 gel became infected with HIV at approximately a 50% higher rate than women who used the placebo gel.

CDC has released a "Dear Colleague" letter that summarizes the findings and implications of the UNAIDS study. The letter is available on the World-Wide Web, <http://www.cdc.gov/hiv>; a hard copy is available from the National Prevention Information Network, telephone (800) 458-5231. Future consultations will be held to re-evaluate guidelines for HIV, STDs, and pregnancy prevention in populations at high risk for HIV infection. A detailed scientific report will be released on the Web when additional findings are available.

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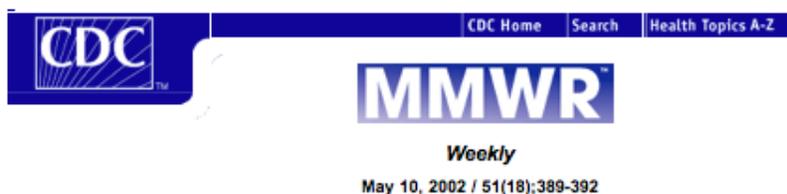
1. van Damme L. Advances in topical microbicides. Presented at the XIII International AIDS Conference, July 9--14, 2000, Durban, South Africa.

* Use of trade names and commercial sources is for identification only and does not constitute endorsement by CDC or the U.S. Department of Health and Human Services.

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Nonoxynol-9 Spermicide Contraception Use --- United States, 1999

Most women in the United States with human immunodeficiency virus (HIV) become infected through sexual transmission, and a woman's choice of contraception can affect her risk for HIV transmission during sexual contact with an infected partner. Most contraceptives do not protect against transmission of HIV and other sexually transmitted diseases (STDs) (1), and the use of some contraceptives containing nonoxynol-9 (N-9) might increase the risk for HIV sexual transmission. Three randomized, controlled trials of the use of N-9 contraceptives by commercial sex workers (CSWs) in Africa failed to demonstrate any protection against HIV infection (2--4); one trial showed an increased risk (3). N-9 contraceptives also failed to protect against infection with *Neisseria gonorrhoeae* and *Chlamydia trachomatis* in two randomized trials (5,6), one among African CSWs and one among U.S. women recruited from an STD clinic. Because most women in the African studies had frequent sexual activity, had high-level exposure to N-9, and probably were exposed to a population of men with a high prevalence of HIV/STDs, the implications of these studies for U.S. women are uncertain. To determine the extent of N-9 contraceptive use among U.S. women, CDC assessed data provided by U.S. family planning clinics for 1999. This report summarizes the results of that assessment, which indicate that some U.S. women are using N-9 contraceptives. Sexually active women should consider their individual HIV/STD infection risk when choosing a method of contraception. Providers of family planning services should inform women at risk for HIV/STDs that N-9 contraceptives do not protect against these infections.

CDC collected information on types of N-9 contraceptives purchased and family planning program (FPP) guidelines for N-9 contraceptive use. The national FPP, authorized by Title X of the Public Health Service Act, serves approximately 4.5 million predominantly low-income women each year. Program data for 1999 were obtained from all 10 U.S. Department of Health and Human Services (HHS) regions on the number of female clients and the number of female clients who reported use of N-9 contraceptives or condoms as their primary method of contraception. CDC obtained limited purchase data for 1999 for specific N-9 contraceptives and program guidelines from eight state/territorial FPPs within six HHS regions. State health departments, family planning grantees, and family planning councils were contacted to request assistance in collecting data on purchasing patterns of the 91 Title X grantees; of the 12 FPPs that responded, eight provided sufficient data for analysis.

In 1999, a total of 7%--18% of women attending Title X clinics reported using condoms as their primary method of contraception. Data on the percentage of condoms lubricated with N-9 were not available. A total of 1%--5% of all women attending Title X clinics reported using N-9 contraceptives (other than condoms) as their primary method of contraception (Table 1). Among the eight FPPs that provided purchase data, most (87%) condoms were N-9--lubricated (Table 2). All eight FPPs purchased N-9 contraceptives (i.e., vaginal films and suppositories, jellies, creams, and foams) to be used either alone or in combination with diaphragms or other contraceptive products. Four of the eight clinics had protocols or program guidance stating that N-9--containing foam should be dispensed routinely with condoms; two additional programs reported that despite the absence of a clinic protocol, the practice was common. Data for the other two programs were not available.

Reported by: The Alan Guttmacher Institute, New York, New York. Office of Population Affairs, U.S. Dept of Health and Human Services, Bethesda, Maryland. A Duerr, MD. C Beck-Sague, MD. Div Reproductive Health, National Center Chronic Disease and Public Health Promotion; Div of HIV and

AIDS Prevention, National Center HIV/AIDS, STDs, and TB Prevention; B Carlton-Tohill, EIS Officer, CDC.

Editorial Note:

The findings in this report indicate that in 1999, before the release of recent publications on N-9 and HIV/STDs (4,6,7), Title X family planning clinics in the U.S. purchased and distributed N-9 contraceptives. Among at least eight family planning clinics, most of the condoms purchased were N-9-lubricated; this is consistent with trends in condom purchases among the general public (8). The 2002 STD treatment guidelines state that condoms lubricated with spermicides are no more effective than other lubricated condoms in protecting against the transmission of HIV infection and other STDs (7). CDC recommends that previously purchased condoms lubricated with N-9 spermicide continue to be distributed provided the condoms have not passed their expiration date. The amount of N-9 on a spermicide-lubricated condom is small relative to the doses tested in the studies in Africa and the use of N-9-lubricated condoms is preferable to using no condom at all. In the future, purchase of condoms lubricated with N-9 is not recommended because of their increased cost, shorter shelf life, association with urinary tract infections in young women, and lack of apparent benefit compared with other lubricated condoms (7).

Spermicidal gel is used in conjunction with diaphragms (1); only diaphragms combined with the use of spermicide are approved as contraceptives. The respective contributions of the physical barrier (diaphragm) and chemical barrier (spermicide) are unknown, but the combined use prevents approximately 460,000 pregnancies in the United States each year (1).

The findings in this report are subject to at least two limitations. First, data on specific products and patterns of contraceptive use were limited; CDC used a nonrepresentative sample of regions and states that voluntarily provided data, and specific use patterns of the contraceptives could not be extrapolated from these data. Second, data correlating use of N-9 contraceptives with individual HIV risk were not available.

Prevention of both unintended pregnancy and HIV/STD infection among U.S. women is needed. In 1994, a total of 49% of all pregnancies were unintended (9). Furthermore, 26% of women experience an unintended pregnancy during the first year of typical use of spermicide products (1). In 1999, a total of 10,780 AIDS cases, 537,003 chlamydia cases, and 179,534 gonorrhea cases were reported among U.S. women. Contraceptive options should provide both effective fertility control and protection from HIV/STDs; however, the optimal choice is probably not the same for every woman.

N-9 alone is not an effective means to prevent infection with HIV or cervical gonorrhea and chlamydia (2,7). Sexually active women and their health-care providers should consider risk for infection with HIV and other STDs and risk for unintended pregnancy when considering contraceptive options. Providers of family planning services should inform women at risk for HIV/STDs that N-9 contraceptives do not protect against these infections. In addition, women seeking a family planning method should be informed that latex condoms, when used consistently and correctly, are effective in preventing transmission of HIV and can reduce the risk for other STDs.

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Table 1

TABLE 1. Number of women using male condoms or nonoxynol-9 (N-9) products as their primary method of contraception, by Title X Family Planning Region — United States, 1999

Region*	No. of women served	Male condoms		N-9 products†	
		No.	(%)	No.	(%)
I	179,705	27,726	(15)	1,251	(1)
II	404,325	73,069	(18)	21,515	(5)
III	487,502	73,088	(15)	4,807	(1)
IV	1,011,126	93,011	(9)	29,630	(3)
V	522,312	61,756	(12)	2,489	(1)
VI	478,533	40,520	(8)	11,212	(2)
VII	238,971	15,949	(7)	1,386	(1)
VIII	133,735	15,131	(11)	4,885	(4)
IX	672,362	109,678	(17)	14,547	(2)
X	186,469	17,320	(9)	1,275	(2)
Total	4,315,040	527,248	(12)	92,997	(2)

*Region I=Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, Vermont; Region II=New Jersey, New York, Puerto Rico, Virgin Islands; Region III=Delaware, District of Columbia, Maryland, Pennsylvania, Virginia, West Virginia; Region IV=Alabama, Florida, Georgia, Kentucky, Mississippi, North Carolina, South Carolina, Tennessee; Region V=Illinois, Indiana, Michigan, Minnesota, Ohio, Wisconsin; Region VI=Arkansas, Louisiana, New Mexico, Oklahoma, Texas; Region VII=Iowa, Kansas, Missouri, Nebraska; Region VIII=Colorado, Montana, North Dakota, South Dakota, Utah, Wyoming; Region IX=Arizona, California, Hawaii, Nevada, American Samoa, Guam, Mariana Islands, Marshall Islands, Micronesia, Palau; Region X=Alaska, Idaho, Oregon, Washington.

†Primary method of contraception reported by these women was one of the following: spermicidal foam, cream, jelly (with and without diaphragm), film, or suppositories.

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Table 2

TABLE 2. Number of nonoxynol-9 (N-9) contraceptives purchased by Title X Family Planning Programs in selected states/territories, 1999

State/territory	No. of clients served	Physical barrier method		N-9 chemical barrier methods				
		Condoms with N-9	Condoms without N-9	Gel	Vaginal			Foam
					Film	Insert	Jelly	
Puerto Rico	15,103	148,072	5,000	12,900	0	NA*	12,841	2,400
New York†	283,200	1,936,084	NA	0	73,788	NA	3,112	23,830
West Virginia	60,899	1,300,000	9,360	0	0	NA	1,200	9,900
Florida	193,784	3,920,000	560,000	0	468,720	NA	5,760	25,920
Tennessee	111,223	2,865,160‡	717,088	0	94,500	12,528	756	2,758
Michigan	166,893	631,000	254,000	0	0	NA	1,000	1,200
Oklahoma	58,392	708,480	0	0	394,560	NA	1,200	0
Oregon	57,099	151,900	276,000	345	25,764	2,074	272	3,007

*Not available.

†41 of 61 grantees responded.

‡Purchasing by family planning and sexually transmitted disease programs are combined and cannot be separated.

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