STARTER KIT

University of California, San Francisco
AIDS Health Project
in collaboration with
Allen/Loeb Associates

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>
> Dilley, J.W., Woods, W.J., Loeb, L., Lihatsh, T., Nelson, K., Sheon, N., et al. (2007). Brief cognitive counseling with HIV testing to reduce sexual risk among men who have sex with men. *Journal of Acquired Immune Deficiency Syndrome*, *44* (1), 569–77.

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Introduction to the Personalized Cognitive Counseling (*PCC*) Intervention

Personalized Cognitive Counseling (PCC) is a single-session counseling intervention designed to reduce unprotected anal intercourse [UAI] among men who have sex with men (MSM) who are repeat testers for HIV. ***PCC*** focuses on the person's self-justifications (thoughts, attitudes, and beliefs) used when deciding whether or not to engage in sexual behavior that can transmit HIV. This 30- to 50-minute intervention is conducted as the counseling component of *Counseling, Testing, and Referral Services* (*CTRS*) for MSM who are screened eligible for ***PCC***. Male clients that present for HIV counseling and testing who screen eligible to receive ***PCC***, are those who:

- Previously tested for HIV,
- Result showed seronegative on that test,
- Had UAI since their last test,
    - with a male who was not their primary partner, &
    - that partner's serostatus was positive or unknown.

PCC is for those who already have a basic understanding of how HIV is transmitted. Additionally, while a moderate degree of denial of risk does not mean a client cannot participate in ***PCC***, men who truly do not feel at risk or know how HIV is transmitted are not suitable for ***PCC***. An educational or other behavioral intervention like *RESPECT* or prevention case management like *CRCS* would be more appropriate in these cases.

The goal of ***PCC*** is to help clients avoid future episodes of unprotected anal intercourse with partners of unknown or positive HIV status. ***PCC*** encourages the client to explore his reasons or self-justifications (thoughts, attitudes, and beliefs) for engaging in risky sexual behaviors and to develop strategies to avoid future episodes of UAI with partners of unknown or positive HIV status. The process of ***PCC*** is to identify the specific thoughts used by the client when he decided to engage in UAI, aid him in reconsidering those thoughts, and create an opportunity for him to plan for safer ways to think about and behave in future sexual situations.

Once the client is determined eligible for ***PCC,*** the counselor assists the client in selecting a recent memorable episode of UAI (Step 1). With this specific episode in mind, the client is asked to complete the ***PCC*** questionnaire, which generally assists the client in recalling thoughts related to the UAI episode (Step 2). After the client completes the questionnaire, the counselor helps the client talk about the UAI episode in detail, including his thoughts before, during, and after the UAI episode (Step 3). Throughout this narrative, the counselor asks questions to make the story clear and begins identifying the thoughts and feelings that may have affected the client's behavior. The counselor helps the client to identify the thoughts and feelings he was having and how they are associated with his decision to engage in the UAI episode (Step 4). Finally, the counselor asks the client what he will do in the future and supports his constructive plans (Step 5).

Development of *PCC*

PCC was developed and tested at the AIDS Health Project (AHP), a major provider of HIV testing and counseling services located in San Francisco. By the mid-1980s, the AHP's program data showed that many MSM who were counseled and tested for HIV were getting tested multiple times and receiving prevention counseling each time but were continuing to engage in high-risk sexual behavior. Data on seroconversion showed that the rate of new HIV infection among the men who were testing repeatedly was almost three times that of men who had not received multiple HIV tests. The AHP recognized the need to provide a different counseling approach for repeat testers who engaged in risky behavior. With a team of researchers including AHP staff, the agency developed and tested ***PCC***, which was shown to significantly reduce high-risk sex among repeat testers.

Conceptual Framework of *PCC*

Development of the ***PCC*** intervention was based on the work of cognitive psychologist Ron Gold and colleagues (see references in **Appendix 1**). Gold studied how people make risky decisions in spite of knowing the risks. He hypothesized that the decision to engage in high-risk sex is allowed to happen when the person rationalizes the potential risk through "self-talk" that minimizes the known risk, which is referred to as *self-justifications*.

Gold proposed that during *on-line thinking*—thinking in the moment during a sexual encounter–individuals use self-justifications to rationalize giving themselves permission to engage in risky sexual behavior. In *off-line thinking*—thinking that occurs away from the immediacy of a sexual encounter—the individual's thinking is more realistic about risks and their consequences. Cognitive theories of behavior suggest that helping an individual consider his on-line self-justifications in an off-line state may help prevent future risky behavior in the on-line state.

Research Findings

Two randomized controlled studies at the AHP have established that ***PCC*** reduces episodes of UAI in the target population of MSM repeat testers. In the first study (Dilley et al., 2002), ***PCC*** was delivered by licensed mental health professionals trained in the intervention. Participants included 248 MSM. Seventy-six percent of the men were Caucasian and 24 percent were men of color (Asian, African American, Latino, and Other). Each of the men had a history of at least one previous negative HIV test result and self-reported UAI in the previous 12 months with non-primary partners of unknown or discordant HIV status. Two intervention groups received standard HIV counseling and testing plus ***PCC***, while two control groups received only standard HIV counseling and testing. Follow-up was at 6 and 12 months. The results showed that men who received the single session of ***PCC*** significantly reduced their number of episodes of UAI more at both 6 and 12 months than did men who received the standard HIV counseling and testing alone.

Recognizing that most CBOs do not have the resources to hire mental health professionals, the researchers designed a second study (Dilley et al., 2007). In this study, ***PCC*** was conducted by paraprofessional counselors who had bachelor's-level education, training in HIV prevention counseling, were certified in HIV counseling and testing, and had a minimum of one year's experience providing HIV counseling and testing. Before providing ***PCC***, the counselors went through extensive role-play training in conducting the intervention.

Participants included 305 MSM. Sixty-seven percent of the men were Caucasian and 33 percent were men of color. All men had a history of at least one previous negative HIV test result and self-reported UAI in the previous 12 months with non-primary partners of unknown or discordant HIV status. Participants were randomly assigned to standard HIV counseling and testing plus ***PCC*** or standard counseling and testing alone. Follow-up was at 6 and 12 months. The results confirmed that paraprofessional counselors using ***PCC*** could bring about the same results as the first study: men who received ***PCC*** plus standard HIV counseling and testing had a greater reduction of UAI episodes than men receiving standard HIV counseling and testing alone.

Reprints of the original publications describing the two studies are included in **Appendix 1** of the Implementation Manual.

How *PCC* Is Different from Other HIV Prevention Counseling

Using ***PCC*** requires not only the learning of new skills, but the "unlearning" of certain routines and assumptions that go with other types of counseling but do not fit with ***PCC***. When learning the intervention, it is useful to highlight what ***PCC*** is, and also what it is *not*. This helps clarify how ***PCC*** fits into the continuum of interventions an agency can provide. It also helps counselors adjust their own expectations of what they are expected to do and how they are to do it. The following summaries describe how ***PCC*** is different from other HIV prevention counseling interventions.

Not primarily educational. ***PCC*** is designed for men who already have a basic understanding of how HIV is transmitted, and know that UAI is risky. Clients who do not understand the basics of HIV transmission are not appropriate for ***PCC*** and should receive an educational intervention instead. While some educational information may be provided, if needed, ***PCC***'s last step emphasizes helping clients use, rather than ignore, what they already know about HIV transmission.

Not an unstructured session led by the client. Sometimes the term "client centered" is used to mean a counseling approach where the client's feelings and concerns guide the session. In contrast, ***PCC*** structures the session to address risk-related thinking. The client's feelings and concerns are important in ***PCC***, and are drawn out and addressed by the counselor, but primarily as they relate to the ***PCC*** steps.

Not directed at soothing any negative feelings the client may have. Counselors sometimes feel a sense of responsibility to make clients feel better in the short term. While ***PCC*** counselors are empathic and concerned about the client, their goal is not to soothe the client. The goal of ***PCC*** is to help the client change his future behavior by reflecting on and reconsidering the thoughts that he used to justify risky behavior. The intervention may result in the client getting in touch with his reality-based anxiety—that is, his anxiety that if he takes risks he may get HIV. This anxiety is seen as constructive because it helps motivate the client to avoid future risk behavior.

Not completed by the counselor handing the client a solution. The ***PCC*** session closes with the counselor asking the client what he will do in future high-risk situations and supporting any constructive plans he mentions.

PCC Core Elements

To achieve outcomes similar to those found in the original research, agencies implementing ***PCC*** need to retain the Core Elements of the intervention. Core Elements are critical components of an intervention's conceptualization and design that are believed to be responsible for the intervention's effectiveness. Core Elements are essential and cannot be discarded, added to, or changed, in order to maintain intervention fidelity and intent.

Based on the original research studies, the following seven Core Elements are considered responsible for the effectiveness of ***PCC***:

Core Element 1: Provide one-on-one counseling focusing on a recent, memorable high-risk sexual encounter.

Core Element 2: Provide the service with counselors trained in HIV counseling and testing and in the ***PCC*** intervention.

Core Element 3: Use the ***PCC*** questionnaire specifically tailored to identify key self-justifications used by clients in the target population.

Core Element 4: Using the questionnaire and discussion, identify specific self-justifications (thoughts, attitudes, beliefs) used by clients in making the decision to engage in the specific high-risk behavior.

Core Element 5: Explore the circumstances and context for the risk episode in detail (before, during, and after event).

Core Element 6: Clarify how the circumstances and self-justifications are linked to the decision to engage in high-risk behavior.

Core Element 7: Guide the clients to re-examine the thinking that led to their decisions to have high-risk sex and identify ways they might think differently, and therefore have protected sex in future potentially risky situations.

PCC Key Characteristics

While *Core Elements* must be maintained, *Key Characteristics* are parts of an intervention (activities and delivery methods) that can be adapted to meet the needs of the agency or target population. ***PCC*** has the following:

Key Characteristic 1: Conduct ***PCC*** in the context of HIV testing and counseling.

When the original research was conducted at the AIDS Health Project, which was already serving the target population, ***PCC*** was implemented within an HIV testing program. Participants were screened when they first requested HIV testing, and then received ***PCC*** in the interval between giving a blood sample and receiving the result. However, ***PCC*** also seems particularly well suited to the following settings: Comprehensive Risk Counseling and Services (CRCS), mental health services, or primary medical care.

Key Characteristic 2: Counseling staff can be paraprofessionals or mental health professionals as long as they are, as specified in the *Core Elements,* trained and experienced HIV test counselors who are also trained in ***PCC***.

Key Characteristic 3: Complete the intervention in **one** 30- to 50-minute session.

The ***PCC*** intervention is designed to be conducted in a single 30- to 50-minute session. However, the intervention could be longer than 50 minutes when needed.

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GETTING STARTED

Assessing Agency Capacity

Before an agency plans implementation of ***PCC***, two activities are necessary: assessing agency capacity and developing the budget. These activities do not happen strictly in the order they appear in the Implementation Manual—they may happen at the same time. These activities appear in this order in the Implementation Manual because they build on one another: capacity issues lead to discussions around budget development.

Agency Capacity Issues

Capacity issues are focused on assessing agency readiness and securing the buy-in of stakeholders. For ***PCC,*** capacity issues focus on agency culture and facilities, staff skills and training, and client referrals and screening.

The following Agency Readiness Checklist can assist an agency in deciding if they are able and ready to conduct ***PCC***. The results of this assessment will help your agency develop an action plan and identify the best use of resources to ensure successful implementation. The ***PCC*** Agency Readiness Checklist includes six key areas:

1. Mission and Organizational Culture
2. Facilities
3. Training and Supervision
4. Staffing
5. Client Referrals and Screening
6. Agency Commitment to Implement ***PCC***

Agencies can use this checklist to identify gaps in their readiness to implement ***PCC*** and assess whether they can address these gaps through training and technical assistance. If all of your responses are in the first two columns, your agency may well be suitable for implementation of ***PCC***. If any of your responses are in the last column, you should consider whether your agency is a good candidate to implement ***PCC*** and whether training and technical assistance can address these issues.

Following is the ***PCC Agency Readiness Checklist.***

PCC Agency Readiness Checklist

1. Mission and Organizational Culture			
***PCC* Requirement**	**Yes**	**Not now, but this can be addressed**	**No, and change is not feasible**
Nonjudgmental regarding MSM. Can we provide counseling services to men who have sex with men in a nonjudgmental, supportive way?			
Cultural competence. Do we provide services to each of the racial/ethnic or cultural groups within the target population we will reach?			
Sex positive. Are we comfortable assuring clients that they can continue to have very satisfying sexual experiences while promoting safer behavior?			
2. Facilities			
***PCC* Requirement**	**Yes**	**Not now, but this can be addressed**	**No, and change is not feasible**
Do we have private office(s) where ***PCC*** can be conducted? (Sessions are up to 50 minutes, so at least one office is needed per client per hour during the hours ***PCC*** will be provided.)			
3. Training and Supervision			

PCC Requirement	Yes	Not now, but this can be addressed	No, and change is not feasible
Do we have regular, ongoing cultural competence training?			
Are our staff members available for 2 days to attend the ***PCC*** training?			
As staff turnover, will new staff be available to be trained?			
Through contracted or in-house staff, can we provide regular clinical supervision meetings to ***PCC*** counselors by ***PCC***-trained clinical supervisor(s)?			
Do agency policies and procedures enable staff to be mandated to receive training and clinical supervision?			

4. Staffing

PCC Requirement	Yes	Not now, but this can be addressed	No, and change is not feasible
Do we have trained and certified HIV test counselors?			
Do we have staff with at least one year experience providing HIV test counseling?			
Do we have HIV test counselors who possess a bachelor's degree in a helping field (such as psychology or social work), or at least two years of college plus two years of pertinent experience or			

have work experience in these fields?			
Do these staff members have knowledge and experience with the target population(s) to be served?			
Are these staff members committed to providing culturally competent services?			
Are these staff members comfortable with and knowledgeable about men who have sex with men?			
Are these staff members comfortable discussing sex frankly using everyday language?			
5. Client Availability			
***PCC* Requirement**	**Yes**	**Not now, but this can be addressed**	**No, and change is not feasible**
Do we have ongoing access through "inreach," outreach, and referrals to clients who are MSM, who have already had at least one previous HIV test, and who have had high-risk sex since the last test?			
6. Agency Commitment to Implement *PCC*			
***PCC* Requirement**	**Yes**	**Not now, but this can be addressed**	**No, and change is not feasible**
Do we have an "intervention champion?" (defined on page 16 of this document)			
Do we have commitment from our community advisory board, and board of directors?			

Do we have commitment from our senior management staff?			
Do we have commitment from coordinator/line staff supervisors?			
Do we have commitment from line staff?			
Do we have commitment from other key partners if applicable (funders, partner agencies, etc.)?			

Buy-In and the Intervention Champion

Getting "buy-in" is crucial because it assures the support of agency administration and allows agency resources to be used for intervention implementation. Buy-in is done best with an intervention champion. The champion is often the program manager but could be a counselor or a team of people. Regardless of the number of champions, the main issue is convincing the agency that implementing ***PCC*** would make the quality of its prevention services better and that the agency is capable of implementing ***PCC***.

A champion is someone within the agency who serves as a link between the administration and staff. The champion needs to be good at answering questions and helping make any changes in organizational structure. The champion can serve as a negotiator of any necessary trade-offs or compromises. The champion becomes the intervention's spokesperson, anticipates the reservations of the staff, and answers questions about the intervention needs and resources. The champion must have excellent knowledge of the intervention including its costs, Core Elements, and Key Characteristics.

The champion can use the marketing materials available in the intervention package, information presented in the Implementation Manual, and the rest of the package to address any questions or concerns about ***PCC***.

Your agency's intervention champion can use the following stakeholders checklist to get support for implementing ***PCC***. The stakeholders include people on your board of directors or executive board, in your community, agency, your staff, or your funding source who have interest in the successful implementation of your intervention.

Stakeholders Checklist

STEP 1: Find out whether or not the community will support ***PCC***.

STEP 2: Identify your stakeholders. These will include:

- Your agency's board of directors/executive board/advisory board
- Staff members from your agency who will have a role in the operation of the intervention
- Administrators who will get support
- Supervisors who will oversee the intervention
- Staff who will interact with clients at any level
- Other likely stakeholders are:
    - Local agencies from where you could recruit clients, counselors, or both
    - Agencies with support groups for MSM
    - Health care providers and mental health professionals serving MSM
    - Social service agencies reaching MSM
    - Organizations of MSM and organizations that may have members who are MSM
    - Organizations that can provide assistance or other resources
    - Agencies, merchants, printers, publishers, broadcasters, and others who can advertise the intervention
    - Agencies that can provide transportation
    - Advisory board to help adapt an intervention to a population
    - Partner agencies that can give information for resource packets
    - Agencies that your agency needs to keep good community or professional relations with
    - Local health department
    - Local medical and mental health associations
    - Your funding source(s)
    - Others

STEP 3: Get stakeholders informed, supportive, and involved by:

A. Informing stakeholders about the intervention:

- Decide in advance what specific roles you want each stakeholder to play, e.g., who will you ask to:
    - Give financial support?
    - Refer MSM to the intervention?
    - Serve as an intervention counselor?
    - Be a resource that you can refer clients to?
    - Join your community advisory board?
    - Help tailor the intervention for your target population?
    - Provide a room where the session can be held?
    - Speak supportively about ***PCC*** in conversations with their associates?
- Send letters to stakeholders to tell them:
    - About ***PCC*** and its importance,
    - Your agency will be making the intervention available,
    - What specific role(s) you think they might play in the success of the intervention, and
    - Offer a chance for them to learn more.
- Call in two weeks and assess their interest. If they are interested, schedule a time to meet (e.g., one-on-one, lunch-and-learn at your agency with a group of other stakeholders, presentation at their agency for several of their staff or association members).
- Hold the meeting and answer questions.

B. Getting their support:

- Describe several specific roles they could play.
- Emphasize the benefits of their involvement to themselves, their agency, the community, and MSM, and answer their questions.
- Invite them to commit to supporting ***PCC*** by taking on one or more roles. Keep track of commitments.

C. Getting them involved:

- Soon after meeting, send a thank-you letter that specifies the role(s) to which they committed. If they did not commit, send a letter thanking them for their time and interest and ask them to keep the letter on file in case they reconsider it later.
- For persons who committed to a role that is important to pre-implementation, put them to work as soon as possible.
- For persons who committed to involvement later in the process, send them brief progress updates and an idea of when you will be calling on their support.
- Hold periodic celebratory meetings for supporters to show your appreciation for valuable contributions, update them on the intervention's progress, and keep them engaged.

Developing a Budget for *PCC*

The second getting started activity is developing the budget. It is expected that ***PCC*** will be embedded within an organization already conducting HIV testing and prevention counseling. For these agencies, ***PCC*** will be an enhancement of services that will entail additional costs. The budget can be done either for the additional costs only, or for the entire costs of the ***PCC*** portion of the agency's budget. Since the latter is the approach most agencies are likely to take, this is the type of sample provided below.

The cost depends on a number of factors, including:

How many *PCC* sessions do you expect to deliver annually?

From this, you can determine how many counselor hours will be needed, how much space you will need, and how much supervisory time and other expenses, including how much of your agency's operating expenses and overhead should be included in the ***PCC*** budget.

Does your staff have the qualifications to deliver *PCC*?

You may find that you have to pay staff a higher wage to meet educational and training requirements. (Staff qualifications are detailed on page 36 of this document.)

Do you have a clinical supervisor at your agency?

You will either need to contract with a qualified clinician (contact your CDC program officer for potential resources), or allocate time from a clinician already at your agency. An in-house clinical supervisor would need to be paid to attend the ***PCC*** training, and to meet weekly with each ***PCC*** counselor.

Do you have a data entry clerk or another staff person who will do the required data entry, or will counselors do their own data entry?

Assuming the CDC funds your ***PCC*** program, you will need staff who record program data on each client. Many agencies find it works best to have the counselors enter the data at the end of each shift. If you choose this option, you will want to add more time to your estimate for the counselors' time. If a data entry clerk or other person will do the entry, they should be represented in the budget.

Do you have regular cultural competence training at your agency or do you have access to trainings?

This is necessary for agencies delivering ***PCC***. If staff members are not comfortable and experienced in counseling MSM, additional training in this area will also be required.

Do you have a private space for conducting *PCC* sessions? Is there enough time available in the space you have?

PCC sessions take longer than most other HIV testing counseling, so you may need to increase your private counseling space, or there may be special scheduling required, which could have cost implications.

Will there be any new outreach to conduct at your agency's expense?

If you are not already conducting sufficient outreach or receiving clients through referral, you may want to consider starting outreach efforts. Outreach to MSM is necessary to recruit the target population into your program. This includes meeting with organizations, meeting with community stakeholders, and conducting outreach in bars, religious organizations, and social organizations that serve MSM. This special outreach may have additional costs, particularly in personnel time.

Will the number of HIV test encounters increase?

If the number of HIV tests your organization conducts will increase when you implement ***PCC***, you will want to estimate the expenses of additional HIV testing kits and lab expenses.

Following is a list of categories and methods of calculating a budget that may help you consider all the budgetary requirements of ***PCC***.

Costs of Implementing the *PCC* Intervention

The following categories are given as a starting point. Use the staffing and payment type appropriate for your agency. If the budget you are developing is for a funding application, thoroughly review the budgeting requirements of the funder, and modify the categories below as needed.

Adjust the staffing to make it appropriate for your agency and your procedures. For example, if an administrative assistant will conduct the required data entry, include this job function in your time estimate for the administrative assistant. If a counselor or another staff person will do the data entry, include additional time for the counselor or other staff person in the budget.

Some costs shown may not be included in your budget depending on your agency. For example, you may not have a Program Coordinator. The individual items in this budget outline should be adapted to your agency.

Salaried Service Staff

	# staff	% time		Salary		
Clinical Supervisor(s)	____	____	X	_____	=	_____
PCC Counselor(s)	____	____	X	_____	=	_____

Or, if clinical supervisor and ***PCC*** counselors are contractual at your agency:

Contractual Staff

	# staff	# hrs/year	Cost/hr.		Contractual cost
Clinical Supervisor(s)	____	____	X ____	=	_____
PCC Counselor(s)	____	____	X ____	=	_____

Other Supervisors, such as:

	# staff	% time		Salary		*PCC* salary
Program Director	____	____	X	_____	=	_____
Project Director	____	____	X	_____	=	_____
Program Coordinator	____	____	X	_____	=	_____
Other management	____	____	X	_____	=	_____

Other Salaried Managerial Staff

	# staff	% time		Salary		*PCC* salary
Admin. Assist	____	____	X	_____	=	_____
Clerical/Secretary	____	____	X	_____	=	_____

Outreach Workers ____ ____ X _____ = _____

Training Costs

Cost of travel to training, lodging, per diem _____
Extra hours for contractual employees, such as clinical supervisor _____

Other Costs

Volunteers _____
Other contractual staff _____
Facilities (rent) _____
Travel _____
Supplies (office, HIV testing, etc.) _____
Other expenses and overhead (utilities, telephone, photocopying, insurance, administrative fees) _____

TOTAL COST _____
Total all the costs for ***PCC*** from this and the previous page.

Time for Counselors and Supervisors

For ***PCC*** counselors' time, estimate one hour per client and estimate the number of clients per week per counselor. Then, estimate supervision time (about one hour per week), training, meeting, and record-keeping time, which could average about one to two hours per week depending on the number of clients and extent of record keeping.

Once you have the hours per week, you can determine the percentage time. For example, if full-time counselors work 40 hours per week, and will meet with four ***PCC*** clients per week and spend two hours on related activities (such as supervision and record keeping), they will spend 6 of their 40 hours per week on ***PCC***, or 15 percent time. Total costs of salaried staff are then determined by multiplying the number of staff at each salary level by the percent time by the salary, and then totaling the costs for the entire staffing category.

Contractors and Consultants

If necessary, include costs related to the use of contractors and consultants. For example, you may want to contract a licensed mental health professional to conduct clinical supervision. You will need to include these costs in your budget. (If you are funded by the CDC, first ask your program officer if clinical supervision resources are available.)

Training

The CDC provides a 2-day training of counselors at no cost to implementing agencies through its Diffusion of Effective Behavioral Interventions (DEBI) project. However,

your agency is responsible travel related expenses (travel, lodging, and meals). Travel expenses and staff time (salaried or contractual) will need to be included in your budget.

Facilities

Estimate the proportion of your clients that will be ***PCC*** clients to determine the total amount of the facilities to charge to the ***PCC*** budget. For example, if 10 percent of your clients are anticipated to be ***PCC*** clients and annual office rent is $30,000, then the rental cost charged to the ***PCC*** budget would be $3,000. If additional private meeting spaces need to be rented exclusively for conducting ***PCC*** sessions, this amount would go into the budget as well. If your agency conducts HIV testing and counseling at more than one site and you plan to reach ***PCC*** clients at those facilities, calculate the cost for each facility.

Travel

Travel to recruit clients and travel to provide ***PCC*** at alternate sites should all be included in your budget when applicable, and include travel expenses to professional conferences for staff, where appropriate.

Supplies

HIV test kits and other testing supplies for ***PCC*** clients would ordinarily be a separate budget item. Other office supplies and equipment directly connected with implementing ***PCC*** may go in the supplies or equipment categories, or included in "Other Expenses and Overhead," as described below.

Other Expenses and Overhead

If ten percent of your clients are anticipated to be ***PCC*** clients, if permitted by your funding agency you may decide to apportion your other expenses, such as photocopying, utilities, telephone, maintenance, insurance, and other overhead to the ***PCC*** project. Laboratory fees and transport fees may be included in this category as well.

PCC Sample Budget

Following is one example of a ***PCC*** budget. This is for the purpose of illustration only—every agency will have a different budget, so use your experience to develop a budget that is accurate for your agency. Remember to thoroughly review the budgeting requirements of any agency you may be applying to for funding.

This budget assumes a moderate level of salaries and program costs. Obviously, salaries and other costs will vary from program to program depending on your geographical area and other variables. In your budget, use realistic costs—higher or lower than the example—based on the true costs of operating an agency in your geographical area.

Salaried Service Staff

	# staff	% time	Salary/Benefits	***PCC*** portion
PCC Counselor	2	15%	2 @$45,000 = $90,000	$13,500

Notes: In the example above, the budget is determined with the expectation that full-time counselors work 40 hours per week, and will be seeing four ***PCC*** clients per week and spending two hours on related activities such as supervision and record keeping, they are 6/40 time on ***PCC***, or 15 percent time.

Contractual Staff

	# staff	Hours per year	Cost per hour	Contractual cost
Clinical Supervisor(s)	1	135	$100	$13,500

Other Salaried Managerial Staff

	# staff	% time	Salary/Benefits	***PCC*** portion
Program Director	1	5%	$85,000	$4,250
Program Coordinator	1	15%	$60,000	$9,000

Other Nonsupervisory Staff

	# staff	% time	Salary/Benefits	***PCC*** portion
Receptionist	1	15%	$40,000	$6,000

Training Costs

PCC trainings are provided at no cost through the CDC's DEBI project; however, transportation, meals, and lodging have to be figured into the budget.

Travel for four staff @ $250 each	$1,000
Lodging, two nights, for four staff @ $100 each	$400
Per diem and misc. expenses for 4 staff @$200 each	$800

Rent and Utilities

Rent	$3,600
Utilities	$540

Note: This is calculated by apportioning 15 percent of the testing program's rent and utility expenses to ***PCC***. The total rent is $24,000 and the total utilities are $3,600.

Costs Except for Overhead

$13,500	for counselors	
$13,500	for clinical supervisor	
$6,000	for receptionist	
$4,250	for program director	
$9,000	for program coordinator	
$2,200	for lodging and travel costs related to training	
$3,600	for rent	
$ 540	for utilities	
	Subtotal:	$52,590

Overhead

Overhead	$7,888.50

Note: Includes insurance, office supplies, bookkeeping, routine travel, etc., and calculated as 15 percent of total personnel, rent, utilities, and supplies.

Total cost: $60,478.50

PRE-IMPLEMENTATION

Introduction to Pre-Implementation

Once your agency has completed **assessing agency capacity and developing the budget**, you can begin the pre-implementation phase, which prepares the implementing agency to conduct the intervention. It is during this period that your agency should develop a timeline for implementation, identify or hire the appropriate staff to implement ***PCC***, compose a community advisory board, develop a monitoring and evaluation plan, and make changes to the intervention to fit your agency's target population, if needed. Each of these topics is discussed in this section.

PCC Implementation Timeline

(Times suggested are approximate and will vary from agency to agency.)

1. Conduct agency readiness assessment (Months 1–2)

The *Agency Readiness Checklist* (pages 13-16) identifies issues that should be addressed before implementing ***PCC***.

2. Select or hire staff to be trained, (Months 3–5)

The *Staff Qualifications*, included on page 36 of this document, spell out the skills and education needed to be a ***PCC*** counselor or a clinical supervisor.

3. Acquire or schedule additional office space, if required (Months 3–5)

Because the ***PCC*** intervention takes longer than many HIV test counseling protocols, agencies may need to arrange for additional private counseling space.

4. Plan additional efforts to find clients, if required *(Months 3-5)*

If the *Agency Readiness Checklist* identifies a need for additional efforts to reach more ***PCC*** clients, your agency may need to work with other agencies to get referrals or conduct outreach to recruit clients for ***PCC***. A plan on how to do this, including how you will do "inreach" (reaching into your current client pool and drawing out those eligible for ***PCC***) needs to be developed.

5. Train counselors and clinical supervisor (Month 6)

Once the arrangements have been made to offer ***PCC*** and the staff members are available, counselors and the clinical supervisor must attend a ***PCC*** Training of Counselors (TOC).

6. Orient other staff and agency partners (Months 3-6)

Before ***PCC*** is instituted, other agency staff members (receptionists, nurses, outreach staff, staff conducting monitoring and evaluation, etc.) need to know about ***PCC***. They may be providing information to clients, and/or screening and referring clients. Likewise, agency partners and stakeholders—those who refer clients, and those who provide other needed services in tandem—need to be informed about the new service.

7. Begin implementation of *PCC* (Month 7, then ongoing)

Following training, implementation should begin as soon as possible, to take advantage of the momentum provided by the training, and to reinforce the learning provided by the training.

8. Implement quality assurance (Month 7, then ongoing)

Quality assurance consists of 1) weekly supervision sessions, supplemented by Q&A and troubleshooting as needed; 2) use of the ***PCC*** *Steps Checklist* (on page 90 in the Implementation Manual); and 3) use of the ***PCC*** *Satisfaction Questionnaire* (on page 91 in the Implementation Manual).

9. Check-in for "course adjustment" and troubleshooting (Month 8, then ongoing)

For the first three months of implementation, or longer if needed, the agency's entire ***PCC*** team should meet semi-monthly to identify any issues that need to be addressed. Consultation with your CDC Project Officer and/or submitting a request for capacity building assistance (CBA) can be initiated when needed.

10. Implement any needed adjustments (Month 8, then ongoing)

Anticipate that some fine-tuning and problem solving will need to take place in the first few months of implementation.

11. Finalize implementation of PCC with standard level of clinical supervision (Ongoing)

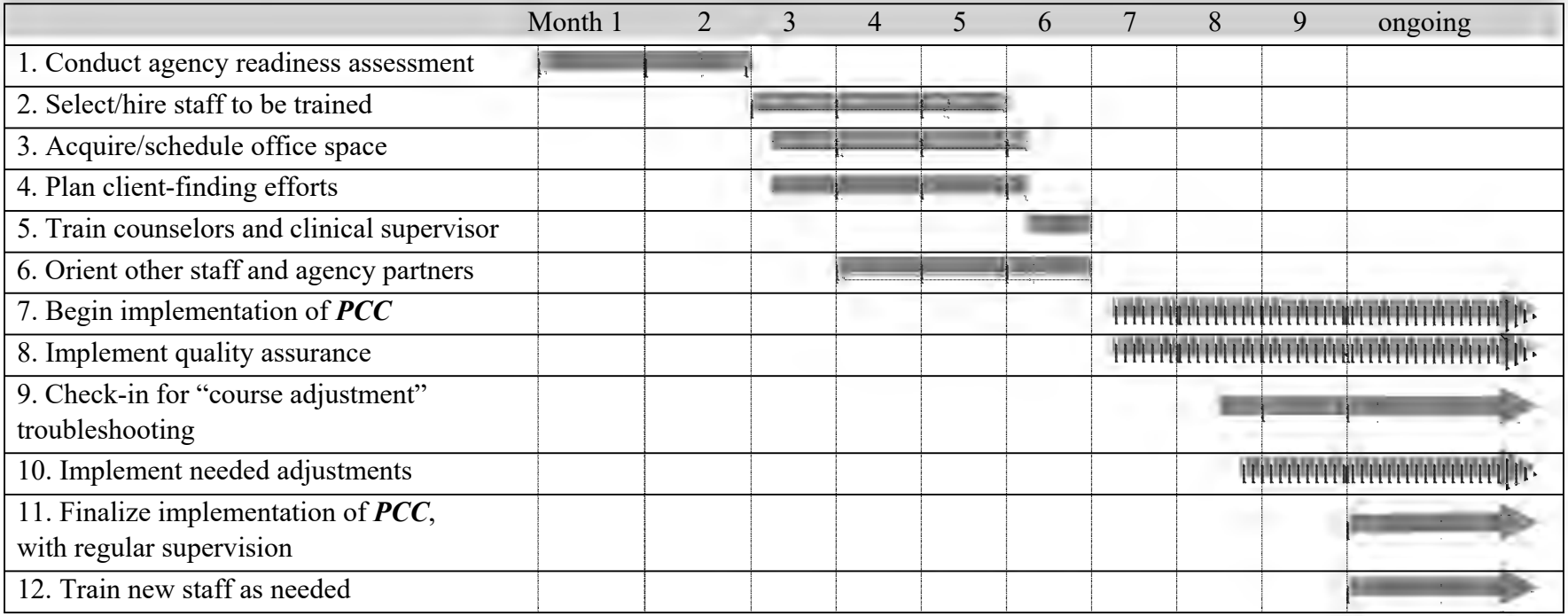
About six months into implementation, it is anticipated that the initial problems will have been identified and corrected, the staff will be familiar and comfortable with delivering ***PCC***, and the referral processes will be in place. The frequency of supervision sessions can be reduced to monthly, and the use of the ***PCC*** *Steps Checklist* can be reduced to every fourth client, if desired. The ***PCC*** team check-in can become a part of regular staff meetings. Regular ongoing training in cultural competence should still continue.

12. Train new staff as needed (Ongoing)

Staff turnover will necessitate arranging training for the new staff from a ***PCC*** trainer, and more intensive supervision for the new staff will be required for their first three months of work. Contact your CDC Project Officer or health department liaison to schedule training. In the mean time, new staff should become familiar with the ***PCC*** Implementation Manual. Counselors **should not** conduct ***PCC*** until they are formally trained.

PCC Sample Timeline (Actual time required will vary from agency to agency)

Note: A solid bar means the activity stops at the end of the indicated period. A bar that has an arrow on the right indicates an ongoing activity.



PCC Intervention Implementation Summary

The Implementation Summary provides you with an overview of the resources, activities, and deliverables needed to successfully implement ***PCC***. It can be useful in planning your implementation and also in verifying that the intervention has been implemented completely.

Inputs *Inputs are the resources needed to operate a program to conduct the intervention activities.*	**Activities** *Activities are the actions conducted to implement an intervention.*	**Outputs** *Outputs are the deliverables or products that result when activities are conducted. Outputs provide evidence of service delivery.*
PCC-specific screening protocols and system to integrate the ***PCC*** intervention into flow of client in HIV testing program services	Screen all male clients who present for HIV testing services for selection criteria: MSM, previous HIV testing, HIV-negative, and unprotected anal intercourse since last test	At least 90% of all male clients requesting HIV testing services are screened for counseling with ***PCC***
Private space to conduct the one-on-one ***PCC*** intervention	Counsel ***PCC*** clients in a private space	100% of all clients counseled with ***PCC*** rate their counseling session as having taken place in a private space
30 to 50 minutes dedicated time for counseling each ***PCC*** client	Counsel each ***PCC*** client in a 30- to 50-minute one-on-one ***PCC*** session	90% of all clients counseled with ***PCC*** completed the counseling in not less than 30 minutes and not more than 50 minutes
PCC counselor(s) and clinical supervisor of ***PCC*** counselor(s)	Ensure competency of HIV test counselors to conduct ***PCC*** in the context of HIV testing, including ongoing review of counseling sessions by a ***PCC*** clinical supervisor	30% of ***PCC*** sessions are reviewed by the ***PCC*** clinical supervisor and 80% of the sessions reviewed receive a satisfactory rating by the client and the counseling supervisor
Time for supervision of ***PCC*** counselors	***PCC*** clinical supervisors provide 30-minute review of sessions and guidance to ***PCC*** counselors for a subset of all clients counseled using ***PCC***	***PCC*** clinical supervisors and ***PCC*** counselors conduct a weekly supervision session lasting at least 60 minutes reviewing at least 25% of each counselor's ***PCC*** sessions
Sensitivity to issues involved in working with MSM, and cultural competence with populations served	Counselors distribute post-counseling client satisfaction form; provisions made for clients to return this anonymously	60% of clients report a high level of client satisfaction with services received

Implementing *PCC* in an Existing Service Agency

Embedding

Because the ***PCC*** intervention is intended to be offered along with HIV testing, it should be embedded within a service called "counseling and testing." As recommended by CDC guidelines, these services often include additional components such as consenting processes, referral processes, partner notification services, and individual or group education programs. In addition, local laws and organizational policies will be applied to regulate the ***PCC*** intervention.

To effectively use this package, providers are encouraged to embed the ***PCC*** intervention within their service or program in a way that minimizes disruption and changes to the protocol.

New Programs

If ***PCC*** is to be implemented as part of a completely new service program, the complexity of the process is greatly increased. It is beyond the scope of the ***PCC*** Implementation Manual to describe how to set up and operate an HIV testing and counseling program from the ground up. It is recommended that you contact the CDC and/or your state and local health department for assistance.

Enhancement

Many agencies that will implement ***PCC*** will already be serving the target population and will have most of the required systems in place, including ongoing cultural competence training, regular supervision of counselors, and a referral network and/or outreach program that brings in members of ***PCC***'s target population.

Implementation of ***PCC*** will involve enhancing the agency's services through training the counselors and clinical supervisor(s) in ***PCC***, adding additional quality assurance (supervision, fidelity forms, and client feedback form), and in some cases, increasing recruitment of clients eligible for ***PCC***.

Screening

If all HIV test counselors who provide services to MSM are trained in ***PCC***, they can conduct the screening in the initial risk assessment and then seamlessly transition into providing ***PCC***. If only some of the counselors are trained in ***PCC***, those who are not trained need to learn how to screen clients, and then make a referral to a ***PCC*** counselor. This may not be practical when a ***PCC*** counselor is not immediately available. It may then be necessary for the counselor to provide a conventional HIV counseling and testing session instead of ***PCC***. The client may not want to defer his testing, and it is important not to lose the opportunity to provide the service. If the client appears to be genuinely motivated, it may be possible to postpone the testing until a ***PCC*** counselor is available; this would be a case-by-case call.

Quality Assurance

PCC comes with a quality assurance (QA) component, including a checklist to be completed by counselors and a feedback form to be completed by clients. Integrating this into the agency's existing QA plan will take some thought. For example, if you already have clients completing a satisfaction survey, you will want to consider whether you want to substitute the ***PCC*** form, or combine the information on one form for these clients.

Funding

It may be necessary to think through the funding implications of ***PCC***. If the agency is being funded on a per-session basis, additional funds for ***PCC*** will probably be necessary, since the session is usually longer and hence costs a little more to deliver than conventional HIV counseling and testing.

Staff Qualifications, Training, Roles, and Responsibilities

Counselors' Qualifications and Training

Based on the research projects in which ***PCC*** was tested, the necessary qualifications for being a ***PCC*** counselor are:

- Training as an HIV antibody test counselor.
- At least one year of experience providing HIV test counseling.
- Training and experience in a helping field (psychology, social work, counseling).
- Experience with and dedication to pursuing cultural competence with the populations of clients to be served.
- Comfort with and knowledgeable about men who have sex with men.
- Comfort with discussing sex frankly using everyday language.
- Completion of training to learn the ***PCC*** intervention.
- If counselors are to enter required M&E data, they will need training on this.

Counselors' Roles and Responsibilities

- Screen clients for the ***PCC*** intervention. Other staff may also screen clients.
- Conduct the ***PCC*** intervention.
- Complete ***PCC*** *Steps Checklist* (on page 90 in the Implementation Manual).
- Provide clients with ***PCC*** *Satisfaction Questionnaire* (on page 91 in the Implementation Manual) and inform clients on the importance of returning completed questionnaires.
- Review returned ***PCC*** *Satisfaction Questionnaires* from clients.
- Record and enter the NHM&E DS data. Other staff may also enter data.

Clinical Supervisors' Training and Qualifications

- Master's level training as a counselor, social worker, or therapist with a degree in psychology, social work, counseling, or a similar helping field.
- At least one year of experience as a clinical supervisor.
- Completion of training to learn the ***PCC*** intervention. (***PCC*** Clinical Supervisors may be available through the CDC or the CDC can provide names of qualified agencies or people with whom your agency can contract.)

Clinical Supervisors' Roles and Responsibilities

- Provide one hour a week or more of clinical supervision to counselors. Clinical supervision includes review of sessions recordings, discussion of issues raised in ***PCC*** sessions, review of the ***PCC*** *Steps Checklist*, review returned *Satisfaction Questionnaires*, aiding counselors in understanding and dealing with feelings raised by ***PCC*** sessions, and providing feedback and advice to optimize service fidelity and quality.

Program Director/Executive Director/Clinic Manager/Coordinator/etc. Training and Qualifications

Management staff may have different titles, as well as different types of education and training. There is no specific educational background required. The key qualifications are:

- Ability to manage an HIV-related counseling program.
- Knowledge and experience with the target population.
- Overall understanding of ***PCC*** including knowing the target populations, qualifications of staff needed, need for clinical supervision, and relationship to HIV testing.

Program Director/Executive Director/Clinic Manager's Roles and Responsibilities

- Provide leadership and oversight of the implementation of ***PCC***.
- Conduct the implementation steps described in the Implementation Manual, and/or delegate them to others; monitor progress of activities delegated to others and take corrective action as necessary.
- Oversee the other staff and make sure they are performing their duties, i.e., that the ***PCC*** counselors are counseling clients, the clinical supervisor is meeting with counselors weekly, the bookkeeper is recording expenses.
- Ensure that ***PCC*** counselors and other staff have the resources necessary to perform their duties. These resources include training, space, time, and day-to-day guidance.
- Oversee budgeting and track expenditure of funds.
- Review process and outcome data and make corrections as necessary.
- Assist with quality assurance through review of data, direct observation, and consultation with staff.

Administrative Staff such as Receptionist, Data Entry Clerk, Bookkeeper's Qualifications and Training

- Past experience in the job or a job with similar duties.

- Data entry clerks, if any, should have training on entering any required M&E data.
- The bookkeeper should be oriented as to which expenses are to be assigned to the ***PCC*** budget.
- The receptionist should have training in cultural competency and be knowledgeable about and comfortable with the target population. If the receptionist is to aid with screening, he or she should have training in the ***PCC*** screening criteria.

Administrative Staff Roles and Responsibilities

- The data entry clerk attends data training to enter any required M&E data using any required software (unless this responsibility is assigned to the counselors).
- The receptionist welcomes clients and orients them to the testing procedures, telling them where to wait, how long they will wait, and answering related questions. In some agencies, the receptionist may conduct part of the ***PCC*** screening and direct the clients to ***PCC*** counselors or schedule ***PCC*** appointments.
- The bookkeeper tracks and accurately records the ***PCC***-related expenses.

Finding Clients: "Inreach," Outreach, and Referrals

This section reviews how to find clients and improve your current efforts. ***PCC*** was originally developed as an enhancement of an existing HIV testing and counseling service that already served the target population. It is assumed that your agency already has MSM in the target population coming to the agency for HIV testing, and that you will be able to reach into this pool of clients and identify candidates for ***PCC***. This is called "inreach." You also may choose to build your organizational linkages to receive more referrals of ***PCC***-eligible men from other agencies. Finally, you may also wish to conduct outreach directly to identify appropriate clients.

Publicity and organizational linkages

When you implement ***PCC***, it is a good time to review your existing marketing and publicity as well as organizational linkages. These are some of the ways that you communicate your mission and programs to the larger community, and recruit members of the ***PCC*** target population. Some important aspects of this are discussed below.

Web sites

- Web sites are increasingly important in disseminating information to the public. You will probably want to revisit your own Web site, along with any other Web sites that describe your services. In addition to the hours for HIV testing and counseling and location where the service is offered, the Web site content should emphasize confidentiality, sensitivity to the needs of MSM, all races and ethnicities are welcome, and a nonjudgmental attitude.
- You may want to state explicitly, "If you are a man who has sex with men, and you are worried about some things you have done since your last HIV test, we would be more than happy to provide another HIV test. Our test counselors do not judge or criticize."
- We do not recommend trying to explain ***PCC*** directly to the public or target populations because it is a counseling intervention that requires training to fully understand. However, the nonjudgmental stance and sensitivity to needs of MSM are worth emphasizing wherever possible.

Brochures and directory listings

- The same kind of language described above should be included in brochures and in print directories. Directories put out by other organizations may be out of date, so it is worth making a special effort to seek them out and update them if necessary.

Where to conduct outreach

- Bars, bathhouses, sex clubs, and areas in gay neighborhoods are all places outreach can be conducted. Sending outreach staff to religious, sports, and recreational events that are frequented by MSM is also a productive strategy. You may also want to place advertisements in both gay and general-readership publications. Some agencies find that posters and flyers are helpful. For more information on outreach to MSM, including guides, materials, and other resources, visit http://www.cdcnpin.org/scripts/hiv/outreach.asp

Linkages

- Linkages to other organizations are a key source of getting a stream of referrals. In addition to outreach programs and medical services, organizations that serve or represent MSM can be important partners. Traditionally, bars, clubs, and bathhouses have been important partners in spreading the word about HIV prevention services, including testing. Other organizations that can be good partners include gay sports clubs, political groups, and religious organizations. If your agency is not in touch with these groups, consider recruiting a community advisory board that has these connections. Their input will aid in terms of sensitivity, as well as help you build linkages in the community.

Planning How to Integrate *PCC* into the Testing/ Counseling Session

Before your agency begins to offer ***PCC***, you will need to decide how you want to integrate it within the process of intake, testing, and counseling that your agency uses. The time to make this plan is after your staff counselors have been trained and are fully conversant with the ***PCC*** intake requirements and the ***PCC*** steps.

Below are some examples to consider as you plan. You can fit ***PCC*** into your service sequence in a variety of ways depending on what works best for your agency. However, if your agency offers ***PCC***, remember that the clients need to be screened, and have time for a private session (some may last up to 50 minutes), and the session needs to be with a trained ***PCC*** counselor.

Example #1

The two agencies that tested ***PCC*** during the REP project (case study agencies) found it fairly easy to integrate ***PCC*** into their systems. In both, clients who present for HIV testing are already asked screening questions to assess risk. The customary risk questions will establish if the client has had UAI since his past HIV test, and if this UAI was with an HIV-positive person or someone whose HIV status was unknown. When this is true for a client, the only remaining question to ask for the purposes of ***PCC*** is if the UAI was with a boyfriend or regular partner (for detail and definitions, see the discussion of screening, beginning on page 57 in the Implementation Manual).

At the case study agencies, the same counselor who does the screening conducts the counseling, so once the client is identified as appropriate for ***PCC***, the counselor initiates the session. At these sites, the ***PCC*** session is conducted before the client is referred to the lab, where the HIV and other STD tests are conducted. So the ***PCC*** takes place immediately before the actual test is given and before the results are given.

Example #2

Another procedure is followed at the AIDS Health Project RNA testing program. At this site, clients who test negative on a regular HIV rapid test, but who have had UAI recently (according to RNA test guidelines) are offered RNA testing. In the process of determining the HIV risk, the ***PCC*** screening questions are asked. Then clients who meet ***PCC***'s entry criteria and RNA testing criteria are oriented to the RNA test procedure. The clients are told they will give a blood sample, and then return for the results on a later day. The clients are also informed that at the time they get the RNA test results, the prevention counselor will talk with them for about 30 minutes.

Then, when clients return for the RNA test results, the ***PCC*** counselor first gives them the results and then conducts the ***PCC*** session.

This procedure has been very well received by clients. Some have wondered if clients would be willing to stay for a counseling session after having received the results, but this has not been a problem.

Options

There are reasonable options that have not yet been tried. For example, if a receptionist or outreach worker conducts the screening, they could identify the clients appropriate for ***PCC*** and then introduce them to the ***PCC*** counselor. Agencies choosing to do this will want to think through how the introduction will take place so that it will be comfortable and convenient for the client.

Another option is to conduct the ***PCC*** session in the waiting period between taking an oral swab or blood sample and reporting the results. While the ***PCC*** session could delay receiving the results for some minutes, this was not identified as a problem by ***PCC*** counselors.

Write it down

Before implementing ***PCC***, it is recommended that each agency write down its plan for integrating ***PCC*** into its service sequence, and that all staff involved be brought together in person to become familiar with the plan. Then, several role-play walk-throughs should be conducted to ensure everyone knows what will happen when and what they will say to the client at each step.

Adjustments

As ***PCC*** is implemented, it is likely that some questions and exceptions will come up, so the service sequence should be revisited weekly until everything works smoothly. Adjustments to the procedure should be documented so that everyone understands them and new staff can be oriented.

Community Advisory Board

The advisory board is made up of individuals from the community your agency serves, who understand the various needs of the community, and who know the best way to effectively communicate with the target population. The advisory board is not absolutely necessary to successfully implement ***PCC***. However, because of the members' unique insights into your target population, the advisory board can be helpful in modifying ***PCC*** for your agency and facilitate making organizational linkages. Assembling an advisory board is not a long or extensive process, and the size of the board will vary. Your agency can pilot the intervention with the board, and the members' feedback can help your agency improve the quality of delivery. Some other ways that the advisory board can assist your agency are by providing ideas about marketing and recruiting. The advisory board may be a valuable resource in making ***PCC*** a culturally appropriate intervention for your community.

Adaptation of *PCC*

PCC has been proven to be a successful intervention for MSM, and has been tested with hundreds of MSM. However, no two communities are exactly alike; therefore, ***PCC*** may need to be modified to fit the needs of your community and agency. Before making any adaptations to the program, your agency is strongly encouraged to deliver the intervention as written with no changes. This will give your agency a better sense of how the session flows, how MSM respond to the program, and how the intervention works for your agency. You may find that the intervention fits your needs perfectly as written. Or, you may find that you will need to adapt ***PCC*** to fit the specific needs of your population.

Considerations to keep in mind when adapting the intervention include the needs of your population, the capabilities and resources of your agency, and the intervention's Core Elements. Adaptation should improve the delivery of the intervention and make the information more accessible for the clients. Adapting does not and should not alter, delete, or add to the Core Elements of ***PCC***. Working closely with your CDC Project Officer, local or state health department, or requesting CBA services will help your agency to make the most appropriate adaptations. Some areas where adaptation may be necessary include:

Populations

When agencies are considering adapting ***PCC*** for other populations, they should take into account the populations' sexual risk behaviors. ***PCC*** was designed and shown to be effective with MSM engaging in UAI with non-primary partners. Thus, the ***PCC*** questionnaire reflects the self-justifications MSM may have in this type of sexual encounter. If ***PCC*** were to be adapted to other populations, extensive background research would be required to identify the self-justifications used by the target population when engaging in unprotected sex. If the findings indicate different self-justifications, the questionnaire would need to be modified and tested through focus groups and other means.

Settings

PCC has been delivered by a community-based organization in their STD testing clinics and by a public health department in a space made available in a gay bathhouse. A mobile van testing facility equipped with an area that is private and soundproof, with trained HIV counselors who are culturally appropriate to the target population, could provide an appropriate setting as well.

A mental health center or prevention case management program with trained HIV counselors, who are culturally appropriate to the target population, and MSM clients requesting HIV testing could also provide an appropriate setting for ***PCC***.

Program Review Board

If CDC will be funding all or part of your agency's implementation of ***PCC***, your agency must follow the "Requirements for Contents of AIDS-Related Written Materials, Pictorials, Audiovisuals, Questionnaires, Survey Instruments, and Educational Sessions in Centers for Disease Control and Prevention (CDC) Assistance Programs" (**Appendix 6**). You also must submit the intervention session, content, and information collection forms you plan to use for approval by a local Program Review Board (PRB). The PRB's assessment will be guided by the CDC's Basic Principles found in 57 Federal Register 26742. If all of your funding for ***PCC*** is from another source, check with that funder for their PRB approvals policy.

It is recommended that you first find out what the local PRB's procedures are and work within them. The PRB may not want to review every page. Your PRB may want an abstract or executive summary of the intervention session to accompany submission of all or part of the materials. If so, copy the section "Introduction to the Personalized Cognitive Counseling (***PCC***) Intervention" from the Implementation Manual. Attaching this text to a copy of the research article (found in **Appendix 1** of the Implementation Manual) may be useful for PRB members who are interested in the scientific evidence supporting the intervention.

Emphasize the activities that are Core Elements of the intervention. Emphasize that these elements are required in order to obtain results similar to those of the original research. Be prepared to answer questions, to provide clarification, or refer PRB members to sections of the package materials for information.

Monitoring and Evaluation

To achieve the best performance and outcome for ***PCC***, agencies should plan to conduct evaluations of the intervention. There are four types of monitoring and evaluation that are relevant to your ***PCC*** program: formative, process monitoring, process evaluation, and—when possible—outcome monitoring. Formative evaluations are performed during the pre-implementation phase to assess the needs of the target population for ***PCC***. The other three types of monitoring and evaluation—process monitoring, process evaluation, and outcome monitoring—are performed in the Maintenance phase, after the program has been delivered. More information, including guidance on how to develop a monitoring and evaluation plan, on the types of monitoring and evaluation, including sample tools, can be found in the *PCC Monitoring and Evaluation Field Guide.*

Appendix: CDC Required Materials

- CDC Statement on the ABC's of Smart Behavior
- CDC Fact Sheet for Public Health Personnel: Male Latex Condoms and Sexually Transmitted Diseases
- Program Review Panel Guidelines for 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).
- Program Review Panel Instructions for Form 0.113
- Form 0.113
- CDC Statement on Nonoxynol-9 Spermicide Contraception Use, May 10, 2002
- CDC Statement on Study Results of Product Containing Nonoxynol-9

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.

CDC
CENTERS FOR DISEASE CONTROL AND PREVENTION

For more information:
CDC's National Prevention Information Network
(800) 458-5231 or www.cdcnpin.org

CDC National STD/HIV Hotline
(800) 227-8922 or (800) 342-2437
En Espanol (800) 344-7432
www.cdc.gov/std

Fact Sheet for Public Health Personnel:

Male Latex Condoms and Sexually Transmitted Diseases

In June 2000, the National Institutes of Health (NIH), in collaboration with the Centers for Disease Control and Prevention (CDC), the Food and Drug Administration (FDA), and the United States Agency for International Development (USAID), convened a workshop to evaluate the published evidence establishing the effectiveness of latex male condoms in preventing STDs, including HIV. A summary report from that workshop was completed in July 2001 (http://www.niaid.nih.gov/dmid/stds/condomreport.pdf). This fact sheet is based on the NIH workshop report and additional studies that were not reviewed in that report or were published subsequent to the workshop (see "Condom Effectiveness" for additional references). Most epidemiologic studies comparing rates of STD transmission between condom users and non-users focus on penile-vaginal intercourse.

Recommendations concerning the male latex condom and the prevention of sexually transmitted diseases (STDs), including human immunodeficiency virus (HIV), are based on information about how different STDs are transmitted, the physical properties of condoms, the anatomic coverage or protection that condoms provide, and epidemiologic studies of condom use and STD risk.

The surest way to avoid transmission of sexually transmitted diseases is to abstain from sexual intercourse, or to be in a long-term mutually monogamous relationship with a partner who has been tested and you know is uninfected.

For persons whose sexual behaviors place them at risk for STDs, correct and consistent use of the male latex condom can reduce the risk of STD transmission. However, no protective method is 100 percent effective, and condom use cannot guarantee absolute protection against any STD. Furthermore, condoms lubricated with spermicides are no more effective than other lubricated condoms in protecting against the transmission of HIV and other STDs. In order to achieve the protective effect of condoms, they must be used correctly and consistently. Incorrect use can lead to condom slippage or breakage, thus diminishing their protective effect. Inconsistent use, e.g., failure to use condoms with every act of

intercourse, can lead to STD transmission because transmission can occur with a single act of intercourse.

While condom use has been associated with a lower risk of cervical cancer, the use of condoms should not be a substitute for routine screening with Pap smears to detect and prevent cervical cancer.

Sexually Transmitted Diseases, Including HIV

> ***Sexually transmitted diseases, including HIV***
> *Latex condoms, when used consistently and correctly, are highly effective in preventing transmission of HIV, the virus that causes AIDS. In addition, correct and consistent use of latex condoms can reduce the risk of other sexually transmitted diseases (STDs), including discharge and genital ulcer diseases. While the effect of condoms in preventing human papillomavirus (HPV) infection is unknown, condom use has been associated with a lower rate of cervical cancer, an HPV-associated disease.*

There are two primary ways that STDs can be transmitted. Human immunodeficiency virus (HIV), as well as gonorrhea, chlamydia, and trichomoniasis – the discharge diseases – are transmitted when infected semen or vaginal fluids contact mucosal surfaces (e.g., the male urethra, the vagina or cervix). In contrast, genital ulcer diseases – genital herpes, syphilis, and chancroid – and human papillomavirus are primarily transmitted through contact with infected skin or mucosal surfaces.

Laboratory studies have demonstrated that latex condoms provide an essentially impermeable barrier to particles the size of STD pathogens.

Theoretical basis for protection. Condoms can be expected to provide different levels of protection for various sexually transmitted diseases, depending on differences in how the diseases are transmitted. Because condoms block the discharge of semen or protect the male urethra against exposure to vaginal secretions, a greater level of protection is provided for the discharge diseases. A lesser degree of protection is provided for the genital ulcer diseases or HPV because these infections may be transmitted by exposure to areas, e.g., infected skin or mucosal surfaces, that are not covered or protected by the condom.

Epidemiologic studies seek to measure the protective effect of condoms by comparing rates of STDs between condom users and nonusers in real-life settings. Developing such measures of condom effectiveness is challenging. Because these studies involve private behaviors that investigators cannot observe directly, it is difficult to determine

accurately whether an individual is a condom user or whether condoms are used consistently and correctly. Likewise, it can be difficult to determine the level of exposure to STDs among study participants. These problems are often compounded in studies that employ a "retrospective" design, e.g., studies that measure behaviors and risks in the past.

As a result, observed measures of condom effectiveness may be inaccurate. Most epidemiologic studies of STDs, other than HIV, are characterized by these methodological limitations, and thus, the results across them vary widely--ranging from demonstrating no protection to demonstrating substantial protection associated with condom use. This inconclusiveness of epidemiologic data about condom effectiveness indicates that more research is needed--not that latex condoms do not work. For HIV infection, unlike other STDs, a number of carefully conducted studies, employing more rigorous methods and measures, have demonstrated that consistent condom use is a highly effective means of preventing HIV transmission.

Another type of epidemiologic study involves examination of STD rates in populations rather than individuals. Such studies have demonstrated that when condom use increases within population groups, rates of STDs decline in these groups. Other studies have examined the relationship between condom use and the complications of sexually transmitted infections. For example, condom use has been associated with a decreased risk of cervical cancer – an HPV associated disease.

The following includes specific information for HIV, discharge diseases, genital ulcer diseases and human papillomavirus, including information on laboratory studies, the theoretical basis for protection and epidemiologic studies.

HIV / AIDS

HIV, the virus that causes AIDS
Latex condoms, when used consistently and correctly, are highly effective in preventing the sexual transmission of HIV, the virus that causes AIDS.

AIDS is, by far, the most deadly sexually transmitted disease, and considerably more scientific evidence exists regarding condom effectiveness for prevention of HIV infection than for other STDs. The body of research on the effectiveness of latex condoms in preventing sexual transmission of HIV is both comprehensive and conclusive. In fact, the ability of latex condoms to prevent transmission of HIV has been scientifically established in "real-life" studies of sexually active couples as well as in laboratory studies.

Laboratory studies have demonstrated that latex condoms provide an essentially impermeable barrier to particles the size of STD pathogens.

Theoretical basis for protection. Latex condoms cover the penis and provide an effective barrier to exposure to secretions such as semen and vaginal fluids, blocking the pathway of sexual transmission of HIV infection.

Epidemiologic studies that are conducted in real-life settings, where one partner is infected with HIV and the other partner is not, demonstrate conclusively that the consistent use of latex condoms provides a high degree of protection.

Discharge Diseases, Including Gonorrhea, Chlamydia, and Trichomoniasis

Discharge diseases, other than HIV
Latex condoms, when used consistently and correctly, can reduce the risk of transmission of gonorrhea, chlamydia, and trichomoniasis.

Gonorrhea, chlamydia, and trichomoniasis are termed discharge diseases because they are sexually transmitted by genital secretions, such as semen or vaginal fluids. HIV is also transmitted by genital secretions.

Laboratory studies have demonstrated that latex condoms provide an essentially impermeable barrier to particles the size of STD pathogens.

Theoretical basis for protection. The physical properties of latex condoms protect against discharge diseases such as gonorrhea, chlamydia, and trichomoniasis, by providing a barrier to the genital secretions that transmit STD-causing organisms.

Epidemiologic studies that compare infection rates among condom users and nonusers provide evidence that latex condoms can protect against the transmission of chlamydia, gonorrhea and trichomoniasis. However, some other epidemiologic studies show little or no protection against these infections. Many of the available epidemiologic studies were not designed or conducted in ways that allow for accurate measurement of condom effectiveness against the discharge diseases. More research is needed to assess the degree of protection latex condoms provide for discharge diseases, other than HIV.

Genital Ulcer Diseases and Human Papillomavirus

Genital ulcer diseases and HPV infections
Genital ulcer diseases and HPV infections can occur in both male or female genital areas that are covered or protected by a latex condom, as well as in areas that are not covered. Correct and consistent use of latex condoms can reduce the risk of genital herpes, syphilis, and chancroid only when the infected area or site of potential exposure is protected. While the effect of condoms in preventing human papillomavirus infection is unknown, condom use has been associated with a lower rate of cervical cancer, an HPV-associated disease.

Genital ulcer diseases include genital herpes, syphilis, and chancroid. These diseases are transmitted primarily through "skin-to-skin" contact from sores/ulcers or infected skin that looks normal. HPV infections are transmitted through contact with infected genital skin or mucosal surfaces/fluids. Genital ulcer diseases and HPV infection can occur in male or female genital areas that are, or are not, covered (protected by the condom).

Laboratory studies have demonstrated that latex condoms provide an essentially impermeable barrier to particles the size of STD pathogens.

Theoretical basis for protection. Protection against genital ulcer diseases and HPV depends on the site of the sore/ulcer or infection. Latex condoms can only protect against transmission when the ulcers or infections are in genital areas that are covered or protected by the condom. Thus, consistent and correct use of latex condoms would be expected to protect against transmission of genital ulcer diseases and HPV in some, but not all, instances.

Epidemiologic studies that compare infection rates among condom users and nonusers provide evidence that latex condoms can protect against the transmission of syphilis and genital herpes. However, some other epidemiologic studies show little or no protection. Many of the available epidemiologic studies were not designed or conducted in ways that allow for accurate measurement of condom effectiveness against the genital ulcer diseases. No conclusive studies have specifically addressed the transmission of chancroid and condom use, although several studies have documented a reduced risk of genital ulcers in settings where chancroid is a leading cause of genital ulcers. More research is needed to assess the degree of protection latex condoms provide for the genital ulcer diseases.

While some epidemiologic studies have demonstrated lower rates of HPV infection among condom users, most have not. It is particularly difficult to study the relationship between condom use and HPV infection because HPV infection is often intermittently detectable and because it is difficult to assess the frequency of either existing or new

infections. Many of the available epidemiologic studies were not designed or conducted in ways that allow for accurate measurement of condom effectiveness against HPV infection.

A number of studies, however, do show an association between condom use and a reduced risk of HPV-associated diseases, including genital warts, cervical dysplasia and cervical cancer. The reason for lower rates of cervical cancer among condom users observed in some studies is unknown. HPV infection is believed to be required, but not by itself sufficient, for cervical cancer to occur. Co-infections with other STDs may be a factor in increasing the likelihood that HPV infection will lead to cervical cancer. More research is needed to assess the degree of protection latex condoms provide for both HPV infection and HPV-associated disease, such as cervical cancer.

Department of Health and Human Services

For additional information on condom effectiveness, contact:
CDC's National Prevention Information Network
(800) 458-5231 or **www.cdcnpin.org**

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 materialsusing 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 300ee(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

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:

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Weekly
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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.

Reference

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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MMWR

Weekly

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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 No.	Male condoms (%)	N-9 products† No.	N-9 products† (%)
I	176,265	27,726	(15)	1,251	(1)
II	464,325	73,089	(16)	21,615	(5)
III	487,522	73,088	(15)	4,807	(1)
IV	1,011,126	93,011	(9)	29,630	(3)
V	525,312	61,756	(12)	2,489	(1)
VI	478,535	40,520	(8)	11,219	(2)
VII	238,971	10,840	(5)	1,386	(1)
VIII	133,735	15,131	(11)	4,885	(4)
IX	872,362	159,676	(17)	14,547	(2)
X	166,469	17,330	(9)	1,771	(2)
Total	**4,315,040**	**597,246**	**(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, 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: Condoms with N-9	Physical barrier method: Condoms without N-9	N-9 chemical barrier methods: Gel	Vaginal: Film	Vaginal: Insert	Jelly	Foam
Puerto Rico	10,103	148,072	5,000	12,000	0	NA†	12,661	2,400
New York	285,300	1,936,064	NA	0	73,788	NA	3,112	23,830
West Virginia	60,999	1,000,000	9,360	0	0	NA	1,200	9,600
Florida	193,784	3,020,000	560,000	0	468,720	NA	5,760	23,930
Tennessee	111,223	3,865,100	717,000	0	94,500	13,500	750	3,750
Michigan	156,893	931,000	254,000	0	0	NA	1,000	1,200
Oklahoma	58,393	709,650	0	0	304,560	NA	1,000	0
Oregon	57,099	151,900	270,000	NR§	25,764	2,074	772	3,007

*Not available.
†47 of 61 grantees responded.
§Purchasing by family planning and sexually transmitted disease programs are combined and cannot be separated.

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