California Collaborations in HIV Prevention Research: Dissemination Project

INTRODUCTION TO THE DISSEMINATION PROJECT

To support community-based research efforts in California, the State Office of AIDS (OA) and the Universitywide AIDS Research Program (UARP) joined forces in 1998 to provide funding for HIV/AIDS community research collaborations. This program is built upon the collaborative research endeavors initiated by UARP in 1995 and community-based research efforts sponsored by OA. The UARP-OA initiative fosters partnerships among researchers, community-based AIDS service organizations, and local health departments. As a coordinated response to a statewide public health need, it:

- Provides support for evidence-based planning, design, delivery, and evaluation of prevention interventions
- Builds community research capacity
- Disseminates information on HIV/AIDS prevention interventions

UARP and OA have jointly funded 38 community collaborative HIV/AIDS prevention intervention projects. The *California Collaborations in HIV Prevention Research: Dissemination Project* is designed to disseminate information on these research projects and other resources developed through a range of UARP-OA initiatives. All of these materials serve as resources to be used by local health departments, community-based organizations, and research organizations in support of their work in HIV/AIDS prevention and evidence-based planning.

The *Dissemination Project* publishes modules on behavioral risk research, intervention outcome research, and translation research and the Research Summaries. The research modules describe projects that focus on the delivery and content of interventions; the modules do not evaluate prevention intervention effectiveness.

The *Dissemination Project*'s Research Summary series is composed of systematic reviews of HIV/AIDS prevention interventions among peoples of color throughout the United States. These reviews were developed prior to the completion of the UARP-OA– funded community collaborative projects, and thus do not include those California prevention interventions.

The final printed materials in the *Dissemination Project* are Module 7, Module 9, and the second Research Summary. These, as well as all past and future modules and Research Summaries, will be available in PDF format on the UARP website: **http://uarp.ucop.edu.**

GUIDANCE FOR INTERVENTION MODULES

This guidance provides general background and direction on use of the UARP-OA intervention modules. It includes an overview of the literature on community collaborative research, discussion of the issues surrounding adapting and using evidence-based interventions and evaluations in community settings, an overview of the intervention research modules, and guidelines for using the modules. Program planners and coordinators, policy and resource allocation bodies, and researchers and evaluators will be able to adopt some of these materials for their HIV prevention work.

Collaborative Research and Adaptation of Evidence-based Interventions— Current Challenges

One of the critical issues community-based organizations (CBOs) face is the question of how they can best make use of tested interventions with the populations they serve. While

Dissemination Project Publications to Date

- Module 1: *HIV/AIDS Behavioral Risk Research on African American Gay, Bisexual, and MSM*
- Module 2: *The Los Angeles Transgender Health Study*
- Module 3: *Youth Drug Injectors, Needle Exchange Use, and HIV Risk in San Francisco and Santa Cruz*
- Module 4: *Strategies and Tools for Successful Implementation and Evaluation of an Evidence-based Intervention*
- Module 5: *HIV Prevention Outreach Programs in Santa Barbara*
- Module 6: *HIV/AIDS Prevention Intervention Among Urban, At-Risk African Americans*
- Module 7: *HIV Prevention Program for Latino Teen Mothers and Fathers*
- Module 8: *Asian and Pacific Islander MSM HIV Prevention Evaluation Study*
- Module 9: *Multi-Infection HIV Prevention Counseling and Testing Intervention*
- Research Summary: *Systematic Review of HIV Behavioral Prevention Research in Heterosexual African Americans*
- Research Summary: *Systematic Review of Interventions to Prevent HIV Infection in MSM of Color*

The Role of Community Collaborative Research in Building Capacity

A general definition of capacity building is a process or activity that improves the ability of a person or entity to "carry out stated objectives."* In practice, capacity building is often equated with the strengthening of organizations and health systems in order to develop and implement effective health program strategies. Lack of capacity therefore refers to the inability to develop such programs due to a number of issues—inadequate knowledge or information or lack of adequate resources.

The UARP-OA Community Collaborative Research Initiative (CCRI) serves a key role in building the capacity of both CBOs and research institutions to develop sustainable HIV prevention programs. It allows for interaction and a "technology transfer" of information and skills between organizations that have historically not been linked effectively—grassroots community organizations and university-based research institutions. The CCRI initiative allows the opportunity for relationship building between CBOs and academic researchers, thus improving their ability to work toward developing effective interventions.

*A. Lafond, L. Brown, and K. Macintyre, "Mapping Capacity in the Health Sector, *International Journal of Health Planning and Management* 17 (2002): 3–22.

resources are available for implementing interventions that have been shown to be effective with certain populations,[1] little guidance is available on systematic processes for adapting, translating (or tailoring), using, or evaluating these interventions in community settings. In addition, current interventions scientifically proven as effective for community-specific implementation are few and far between—other than those included in the Centers for Disease Control and Prevention's "Compendium of Effective Interventions."

Thus, CBOs face challenges in three broad areas when considering the use of an existing intervention: accessing information on interventions, finding an appropriate intervention, and tailoring the intervention to their own needs, organizational setting, and client population.

Accessing Information on Interventions

How does a CBO wanting to implement a tested intervention begin? How do they access information on interventions?

Easily accessible information and details on tested interventions with related evaluation materials are not always widely available. Thus, in most cases, CBOs rely on information from CBO and public health networks, rather than academic sources.[2]

An alternative strategy is becoming available. Although the process of translating research-based interventions has yet to be studied systematically, the CDC and a network of researchers participating in the Replicating Effective Programs (REP) project have been involved in disseminating research-based interventions and supporting this dissemination with a technical assistance support system based on a train-the-trainers model.[3] CDC has also invested funding into this effort with the implementation of the Diffusion of Effective Behavioral Interventions (DEBI) Project. This approach[4] relies on CBOs' identifying and adhering to the core elements of interventions that report significant behavior change outcomes, while tailoring key characteristics to fit the unique needs and context of their client populations.[5]

Matching the Intervention to the Organization and Population

What are the key issues that organizations consider when deciding on the adoption and/or adaptation of an intervention? A handful of studies identify these points: contextual issues, key characteristics, and features specific to organizations.

Contextual factors that affect the delivery and selection of interventions by CBOs and local health departments include structural or external conditions; cultural norms; client factors; organizational mission, structure, and operations; staffing resources; and the program's relevance, utility, and effectiveness in meeting the needs of populations.[6] Community organizations base their assessments of the appropriateness of an intervention on a number of key characteristics:[7]

- Degree of compatibility with organizational philosophy about HIV prevention
- Perceived relevance to local culture
- Evidence to support its use
- Feasibility of implementing the intervention
- Ability to fill existing service gaps

1. Centers for Disease Control, "Compendium of HIV Prevention Interventions with Evidence of Effectiveness," in *HIV/AIDS Prevention Research Synthesis Project,* Atlanta: CDC, March 1999.
2. H. Barton-Villagrana, B. J. Bedney, and R. L. Miller,, "The Function of Peer Relationships Among HIV Prevention Providers," *Journal of Primary Prevention* 23 (2002), 217–36.
3. M. Neumann and E. Sogolow, "Replicating Effective Programs: HIV/AIDS Prevention Technology Transfer," *AIDS Education and Prevention* 12, supp. A (2000): 35–48.
4. See E. M. Roger, *Diffusion of Innovations,* 4th ed., New York: Free Press, 1995.
5. J. Kelly et al., "Transfer of Research-based HIV Prevention Interventions to Community Service Providers: Fidelity and Adaptation, *AIDS Education and Prevention* 12, supp. A (2000): 87–98.
6. E. Trickett, "Context, Culture and Collaboration in AIDS Interventions: Ecological Ideas for Enhancing Community Impact," *Journal of Primary Prevention* 23 (2002): 157–74.
7. R. Miller, "Innovation in HIV Prevention: Organizational and Intervention Characteristics Affecting Program Adoption," *American Journal of Community Psychology* 29, no. 4 (2001): 621–47.

Also essential to this decision-making process are organizational commitment and positive attitudes toward the intervention, as well as the availability of technical assistance and other resources to support implementation.

Adapting and Translating Interventions

How does a CBO choose an intervention and, once the choice is made, adapt it? As mentioned above, community organizations often gravitate to interventions that are accessible and *known* in the local network of providers. While these interventions may be responsive to community needs, they may not have gone through a rigorous testing to prove their effectiveness. In other cases, a CBO may select a tested intervention because it has credibility with funding organizations, although it may not be specific to their target population.

In either case, an intervention almost always requires some type of tailoring to fit the organization and its constituency. A variety of strategies are employed to enhance cultural appropriateness, including:[8]

- **Peripheral strategies,** such as packaging that focuses on a certain "look" identified as appealing to certain populations
- **Evidential strategies,** use of evidence of the effectiveness of an intervention
- **Linguistic strategies,** translation of the language used in an intervention for a particular population
- **Constituent-involving strategies,** incorporation of the experiences of community members into the intervention
- **Sociocultural strategies,** placement of the intervention within a broad context of health and life issues for a community

Community Collaborative Research—Intervention Outcome Modules

Community collaborative research addresses the issues of replication, adaptation, and use of evidence-based interventions by partnering research scientists and community providers and by ensuring that research, evaluation, and intervention approaches are realistic and grounded in the real world of community organizations working with populations greatly affected by the epidemic.[9] The field of collaborative research facilitates adaptation, development, implementation, and testing of interventions. Use of related materials specifically tailored for populations is a continuing part of this work.

How UARP-OA Collaborative Projects and Intervention Modules Address Current Challenges

UARP-OA collaborative projects are designed to ensure that equal partnerships between academics and community organizations drive the testing and implementation of interventions in community settings. One of the key goals of the *Dissemination Project* is to make materials from evaluation research available to a range of stakeholders: community-based organizations, researchers, and public health providers. The projects presented in the modules represent investigators' work, the collaborative process undertaken, evaluation challenges, and solutions in development of outcome research projects for populations specific to the California context.

Modules include such projects as interventions serving people of color, IDU, youth, women, MSM, and HIV prevention for positives. All modules provide details on the research project, including key findings and collaborative research strategies. The instruments, resource tools, and other sample materials developed to support delivery of the interventions are also included.

In addition to providing key recommendations for community collaborative research within the California HIV prevention programming context, the studies presented in these modules identify methods for placing intervention evaluation in the context of real community settings and tailoring them to the actual people they serve. These collaborative strategies inform the evaluation findings, and in many ways they offer a deeper and more complex perspective on service delivery and evaluation than any one set of outcome findings could provide.

These studies also provide important insights into interventions that are being developed, tested, and implemented, and are therefore useful for health department and CBO intervention planning. Organizations will need to make their own determinations about the appropriateness of the interventions, using the considerations outlined in the preceding section. Applicability will vary depending on the methodological approach and findings from the intervention.

How the Interventions Included in the Modules Have Been Tested—And What This Tells Us

Evaluation research can be charted along a continuum—from initial research on populations to short-term and long-term outcomes of the intervention. Due to their differing purposes and contexts, the UARP-OA evaluation projects include a range of approaches that spans this continuum. The following paragraphs provide an overview of evaluation approaches represented in specific modules and identify how data from various evaluation approaches can be used by stakeholders for intervention design and delivery. Table A links the various modules to the evaluation methods they employed.[10]

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8. M. W. Kreuter et al., "Achieving Cultural Appropriateness in Health Promotion Programs: Targeted and Tailored Approaches," *Health Education & Behavior* 30, no. 2 (2003): 133–46.

9. See K. H. Stanstad et al. (eds.), "Collaborative Community Research: Partnerships Between Research and Practice," *Health Education & Behavior* 26, no. 2 (1999).

10. Although the collaborative research projects illustrated here did not report on intervention efficacy, they did contribute to the understanding of the community context in which such projects occur. Upcoming modules reporting on more-recent research will, as appropriate, include effectiveness data.

Formative evaluation (behavioral risk and context assessment) is used to collect data on consumer populations to ensure that an intervention is targeted to specific behaviors and specific psychological, social, and cultural contexts. Formative data may be used to improve implementation, solve unanticipated problems, and make sure participants are progressing toward desired outcomes.

Process evaluation (intervention implementation) is used to measure the implementation of an intervention in terms of fidelity to core elements, appropriate targeting, and implementation procedures. It describes the components of the intervention, who it is reaching, and how it is implemented. Process data are often used to make sure the intervention is being implemented as planned and is reaching intended populations successfully.

Outcome monitoring (pre- and post-intervention measurement, no control) is used to measure short-term outcomes when control groups are not available or ethical. It is limited in its ability to attribute changes to an intervention, but that can be mitigated somewhat through time-series data collection. Outcome monitoring can be a useful early test for an intervention being implemented at a new site or within a new population. Depending on the number of study participants, this approach can reveal that short-term changes may have taken place, although not necessarily that they are due to the intervention.

Outcome evaluation (quasi-experimental design, nonrandomized control groups) is used to measure short-term outcomes and attribute outcomes to an intervention, in cases where randomization is not feasible. Depending on the number of study participants, this approach can reveal that short-term changes are likely to have occurred as a result of the intervention.

Outcome research (experimental design, randomized control groups) is used to measure short-term outcomes and

Table A Evaluation Methods Employed for *Dissemination Project* Modules

	Evaluation Method				
Module	**Formative Evaluation**	**Process Evaluation**	**Outcome Monitoring**	**Outcome Evaluation**	**Outcome Research**
1: HIV/AIDS Behavioral Risk Research on African American Gay, Bisexual, and MSM	✔	✔			
2: The Los Angeles Transgender Health Study	✔	✔			
3: Youth Drug Injectors, Needle Exchange Use, and HIV Risk in San Francisco and Santa Cruz	✔	✔			
4: Strategies and Tools for Successful Implementation and Evaluation of an Evidence-based Intervention		✔			
5: HIV Prevention Outreach Programs in Santa Barbara	✔	✔			
6: HIV/AIDS Prevention Intervention Among Urban, At-Risk African Americans	✔	✔		✔	
7: HIV Prevention Program for Latino Teen Mothers and Fathers		✔	✔	✔	
8: Asian and Pacific Islander MSM HIV Prevention Evaluation Study	✔	✔	✔	✔	
9: Multi-Infection HIV Prevention Counseling and Testing Intervention		✔			✔

Guidelines on Use of Modules

Purpose

The intervention modules are intended to support and provide a supplemental mechanism for evidence-based planning, design, implementation, and evaluation for intervention services through the use of UARP-OA–funded community collaborative research, including behavioral risk assessments, intervention outcomes, and translation research.

Using the Modules

While best practices for adaptation/translation of tested interventions have yet to be firmly established, the following describes generally the process and practice of using modules and supporting materials for intervention work.

Assessing a Module's Relevance to Your Organization

Step 1: Assess your organization, population, and environmental context, outstanding needs, and available resources with respect to the use of evidence-based prevention and evaluation.

Step 2: Review available intervention and evaluation strategies, findings, and tools in modules, and determine the general fit with or responsiveness to your organization's needs, context, and target population.

Step 3: Based on the results of steps 1 and 2, determine how the relevant intervention or evaluation materials and strategies could best be tailored for use by your organization for the population you intend to serve.

Adapting and Adopting Strategies, Findings, and Materials to Your Organization

Select the components of intervention or evaluation strategies and the materials that speak to specific issues and situations facing your organization, population, and intervention needs. For example, it may be possible to select parts of an evaluation tool that answer questions you have about an intervention or population. Or there may be components of an overall intervention approach that provide relevant support for your work. Also keep in mind that evaluation findings are linked to core elements, so eliminating those elements could impair the effectiveness of the intervention.

- **Behavioral risk findings** can be used to guide program planning and intervention delivery.
- **Intervention findings and materials** can be used for design and delivery of interventions.
- **Tested interventions** can be adapted for implementation in local settings. Maintaining fidelity to core elements is fundamental, although key characteristics should be tailored to local context and population.
- **Research protocols and instruments** can support targeted data collection on local populations and intervention effectiveness, either in their original form or after adaptation to the individual context.
- **Training materials** can support training on delivery of interventions and implementation of program evaluation—again, either as provided or in customized form.
- **Tested interventions and existing interventions** can be linked to provide evidence-based support for existing interventions.

attribute outcomes to an intervention. The control group is randomized in terms of population or site, controlling for the influence of variables unrelated to the intervention. Depending on the number of study participants, this approach can reveal short-term changes as a result of the intervention.

All of the intervention projects tell us about outcome monitoring in community settings, collaborations among multiple partners, tailoring and implementation of interventions, documentation of the process of implementation, consumer responses to interventions, and consumer populations in California.

Evaluation Research in Community Settings

Evaluation of community-based HIV prevention interventions is complex for a number of reasons, including the need for comprehensive service delivery; the challenge of developing linkages among research, public health, and consumer groups; recruitment challenges caused by the multiple contextual factors affecting consumer groups; resource limitations; infrastructure issues; and measurement challenges. In answer to these issues, the UARP-OA Community Collaborative Research Initiative (CCRI) has created opportunities for partnerships between researchers and public health providers to ensure that evaluation and intervention methods are realistic and appropriate to populations being served.

MODULE 9

Multi-Infection HIV Prevention Counseling and Testing Intervention

Principal Investigators:

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Module in a Nutshell

Reports on:

- An intervention addressing a range of STDs, including HIV
- Enhanced counseling and testing
- Experimental design
- Collaboration between CBO and academic researchers

Provides:

- Findings for intervention and comparison groups
- Information materials on STDs for an expanded C&T program
- Recruitment and retention strategies
- Lessons learned from academic-CBO collaboration

CONTENTS

PURPOSE OF MODULE 9

Module 9 presents findings and supporting materials from a randomized controlled trial of a multi-infection counseling and testing (C&T) HIV prevention intervention conducted in San Francisco from 1999 to 2003. David Bangsberg of the HIV Assessment and Prevention Service, San Francisco General Hospital, and Jeffrey Klausner of UCSF and the San Francisco Department of Public Health served as principal investigators for the project. Paula Lum, Center for AIDS Prevention Studies (CAPS), UCSF, was a co-investigator. Edwin Charlebois, Department of Medicine, UCSF, briefly succeeded Dr. Bangsberg in 2001.

The research project assessed the need to expand the standard HIV counseling and testing protocol that is offered to persons seeking HIV testing to include a multi-infection C&T services. The multi-infection C&T intervention also screened for chlamydia, gonorrhea, and hepatitis B and C.

This module describes project development, research methods and tools, and findings, and highlights elements that are unique to collaboration between academic and community partners.

RESEARCH PROJECT

This research project, the Take5! study, was a collaboration of the HIV Assessment and Prevention Service (HAPS) at San Francisco General Hospital, the San Francisco Department of Public Health (SFDPH), and the University of California, San Francisco (UCSF). The study was designed as a randomized controlled trial to test the effectiveness of a multi-infection C&T intervention aimed at reducing HIV-related risk behaviors among those at high risk. Although the study findings did not provide effectiveness data, it did provide a number of key recommendations for community collaborative research, as are outlined below.[1]

Summary and Purpose

STDs have been shown to increase the risk of HIV transmission three- to fivefold.[2]

Background

At the 12th World AIDS Conference in Geneva in 1998, researchers presented evidence that suggests infection with an STD increases the risk of HIV infection. In the United States, data shows that both ulcerative and nonulcerative STDs can increase the risk of HIV transmission three- to fivefold.[2] In addition, HIV infection may also increase the incidence of some STDs, since co-infection with HIV can increase the length of time that an individual's STD remains infectious.[1] While the picture of the relationship between STDs and HIV is grim, recent studies suggest that treatments for some STDs can reduce HIV transmission.[3]

HIV counseling and testing (C&T) programs are a standard component of HIV prevention efforts, and some recent studies have demonstrated the effectiveness of C&T in reducing high-risk behaviors.[4] One study in particular, Project RESPECT, found that brief interactive HIV-STD prevention counseling was associated with an increase in condom use among patients at publicly funded STD clinics.[5]

The Take5! Study combined the established counseling and testing model with the idea of preventing HIV by treating and preventing sexually transmitted diseases. (For this study, in addition to HIV testing, screening also included gonorrhea and chlamydia as well as hepatitis B and C.) The premise was that "multi-infection C&T would diagnose asymptomatic infections in high-risk individuals, and in doing so, would raise risk awareness and have a greater impact on risk behavior than routine HIV C&T." The researchers further hypothesized that emphasizing the topic of multiple infections in the counseling component would be more effective than traditional narrow-focus HIV counseling.[6]

Multi-infection C&T may have a greater impact on risk behavior than traditional HIV C&T.[6]

Goal and Objectives

The Take5! study had three objectives:[1]

- To compare HIV-associated risk and protective behavior among high-risk people randomized to either a multi-infection C&T intervention or standard HIV C&T.
- To determine the effect of the multi-infection C&T on psychological status and other determinants of behavior among high-risk populations.
- To collect biological specimens to test for a variety of sexually transmitted infections* in order to (1) examine risk factors for prevalent HIV infection and co-infection among persons seeking HIV C&T, (2) corroborate self-reported risk behavior during the study period, and (3) estimate the incidence of HIV and STD outcomes to determine the number of study subjects required to evaluate the enhanced intervention using biologic outcomes.

Research Methods

This section describes the research protocol, eligibility and recruitment methods, training, and data collection, including the tools used in these processes (see the appendices). Descriptions of the intervention and control groups are presented below.

*Specimens were collected to test for HIV, hepatitis B and C, gonorrhea (urethral and pharyngeal), and chlamydia.

Research Focus and Protocol

In order to compare the multi-infection prevention C&T to standard HIV C&T, consenting participants were randomly assigned into two groups. Immediately following recruitment, screening, and consent, all participants completed a baseline survey and received pretest counseling. Blood and urine samples and a throat swab were collected from each participant to test for a range of STDs, including HIV.

Participants in both groups were then tracked for six months (including the C&T sessions) with follow-up interviews occurring at three and six months. At six months, a second set of lab tests was done. Participants received pre- and post-test counseling and referrals, treatment for gonorrhea and chlamydia as needed, and hepatitis A and B immunization, if desired.

The researchers hypothesized that interview and biologic data collected over time could be correlated to self-reported risk behaviors, and they could thus explore the effect of the intervention on the incidence of new infections.

Recruitment

Study participants were high-risk individuals seeking HIV tests. Participants were recruited from both the HAPS clinic and methadone clinic at San Francisco General Hospital (SFGH). Recruitment outreach was also conducted at a satellite clinic in the Tenderloin District, where potential participants were given condoms and information about HAPS. Community outreach was subsequently enhanced as the study progressed, to diversify the participant sample. (See the Professional Research Participants sidebar.)

Incentives

- $20 for completing baseline interview
- $10 food voucher for first follow-up visit (test results)
- $15 for follow-up visits 2 and 3
- $20 for final study visit
- $10 voucher for final test-results visit

Participants requesting HIV testing at one of the recruitment sites were approached by a research coordinator and asked if they would be interested in participating in a risk reduction study. The coordinator then explained the risks and benefits of the study to those who were interested, verified that they met the eligibility criteria (Appendix A; also see the next section) and obtained the participant's written consent (Appendix B).

During the course of the study, both staffing levels and workload fluctuated. To avoid counselor burnout, recruitment was curtailed when insufficient staff was available to accommodate the numbers of participants.

Eligibility and Screening

To be eligible for the study, individuals had to be at least 18 years of age or at least 16 and an emancipated minor. They also needed to be planning to remain in the San Francisco Bay Area for at least six months. Finally, they needed to be at high risk for becoming infected with HIV; that is, candidates had to fall into one of the following categories:

- Current injection drug users (IDUs)*
- MSM who had had unprotected sex at least once in last six months
- Heterosexuals with at least two sexual partners in last six months
- Anyone newly diagnosed with a STD within the last year

The research coordinators who handled recruitment used a screening form (see Appendix A), which collected information on gender, race, sexual behaviors, and drug use.

Enrollment

Those who met the eligibility criteria and agreed to participate were required to sign an informed consent form (see Appendix B), which described study procedures, reimbursements (incentives), risks, and benefits. The recruiting staff member and the participant discussed those topics, and the participant was given an opportunity to ask questions before signing the form. A Spanish translator explained the consent form to Spanish-speaking participants and then co-signed the form.

Afterward, participants were given copies of both the informed consent form and the Research Participant's Bill of Rights.†

Randomization

After enrollment, individuals were randomly assigned to either the experimental or the control arm of the study. A computerized random number generator assigned each consecutive ID number to one of the groups in advance. The assignment was then placed in an opaque, sealed envelope that was opened only after a participant had enrolled and been assigned that number. Subjects who declined to participate after learning their assignment were not eligible to reenroll later.

Risks and Confidentiality

Risks and potential discomforts of participating in the study included the following:[1]

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*This criterion was narrowed somewhat during the course of the study. Initially, candidates needed simply to have injected drugs within the previous three months. However, several months into the study that requirement was redefined as only those who, within the last 30 days, had used a syringe that someone else had already used. This amendment was recommended by the counselors, who realized that the counseling's focus on promoting safer injection behavior would be assisted by a more recent occurrence of risky injection behavior.[7]

†See http://www.research.ucsf.edu/chr/Recruit/English.pdf.

Professional Research Participants

One of the team's recruitment strategies was to systematically approach clients of SFGH's methadone clinic. These clients were predominantly white males.

Injection drug users in San Francisco have been well studied and were aware of the monetary reimbursements available to study participants. At the beginning of the study, recruitment at the methadone clinic, supported by word of mouth within the "professional research participant" community, brought significantly more men and IDUs into the study. Anecdotally, it also appears that this group is predominately black or white, and male.

Later, as this participant pool was depleted, more participants with sexual risk factors were recruited.[8]

- **Concerns about privacy.** Participants were assured that every effort would be made to keep their information as confidential as possible. The long-term nature of the project meant that participation in the study could not be anonymous; participants were required to divulge their names and current contact information so that staff could track them over time and follow up. To ensure confidentiality of this information, all consent forms and research records were coded and stored at SFGH in a password-protected computer at the Epidemiology Prevention and Interventions (EPI) Center; this computer was accessible only to study personnel. Summary laboratory, clinical, and epidemiological data were transferred to case report forms that identified the subject only by an ID number, not by name.
- **Discomfort with some of the interview questions.** Due to the personal nature of many of the interview questions, it was anticipated that some participants would be reluctant to answer in some cases. They were told that they could choose not to answer any question and could stop the interview at any time. Referrals for counseling and support were also available.
- **Risk of minor injury or infection from blood tests.** To minimize this risk, certified phlebotomists who were experienced in drawing blood from IDUs using sterile technique were employed to collect all samples.
- **Risk of side effects from therapeutic treatment.** To minimize this type of risk, standard treatment guidelines were used to treat infections and administer vaccines. Vaccine recipients were observed for an appropriate time for acute adverse reactions, and epinephrine was kept at hand in case of anaphylaxis. In addition, participants were informed that in case of injury resulting from their being in the study, treatment would be available and its cost could be covered by UCSF.
- **Risk that negative test results might lead to increased risk behaviors.** The possibility that receiving negative test results could lead to risk behavior disinhibition (due to a false sense of security) was specifically addressed by counseling.
- **Risks to control group through delay in testing and/or treatment.** Control group participants were not screened for STDs or vaccinated for hepatitis until the end of the study (although samples were collected at baseline). To mitigate the risk that these participants could have undiagnosed and untreated STDs or could develop hepatitis, the importance of seeking detection was stressed, and they were given expedited referrals to the San Francisco Department of Public Health STD clinic for gonorrhea and chlamydia screening and treatment (including directions and bus fare) and to the SFGH's General Medical clinic or their primary care physician for hepatitis testing and vaccination.*

Participant Tracking and Follow-Up

Study personnel aggressively tracked participants who did not appear for follow-up appointments.[7] During the baseline interview, the participant filled out a contact form (Appendix C) with names and addresses, phone numbers and times to call, other people and community organizations that might be able to reach them, and best contact methods. A tracking protocol (Appendix D) was developed and used in conjunction with the information collected on the contact form.

When participants failed to show up for appointments, research assistants sent a "no-show" letter, unless the appointment was with a counselor, in which case the counselor called to follow up. To facilitate the search for lost participants, individual staff members established and maintained contacts with community agencies such as homeless shelters, free meal programs, and rehab and detox centers.[8] Research assistants or counselors who had a "relationship" or contacts at a given organization handled all calls to that agency when trying to locate a participant. All efforts to contact a participant were recorded on a tracking form developed for that purpose.

Two interim contacts—a three-month interview and a telephone contact—between the counseling sessions and the final six-month follow-up were built into the study protocol to keep participants involved.

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*The researchers described the need for this approach as follows: "STD screening and treatment and hepatitis vaccination are currently not standard care at HIV testing sites. The central question of the study is to determine whether such screening, treatment and vaccination should become standard care at HIV testing sites. This enhanced referral is designed both to ensure that no control participant receives less than standard care and to preserve the scientific integrity of evaluation."[1]

Training

The HAPS staff members who provided the experimental intervention and the control C&T were already state-certified HIV testing counselors and (at least in the early stages) had also been involved in developing the study protocols (Appendices E and F). Additional training focused on two topics: (1) background on STDs and hepatitis, and (2) training on the research methodology and specifics of study procedures. As staff turnover inevitably occurred during the course of the study, newly hired counselors also needed to be trained on those subjects. These counselors were trained first on standard procedures for HIV testing and counseling at HAPS before being trained for the study.

Understanding of the distinct requirements of research methodology and study procedures was important due to the differing priorities of research and traditional prevention counseling. For example, counselors normally spend unlimited time with a patient, if necessary. But for the study, they were asked to limit sessions to no more than 40 minutes to ensure consistency. Similarly, in their counseling they had always given priority to the patient's needs in relation to risk behaviors, and addressed those needs in their own individual ways. However, for the purposes of the study the counselors needed to follow standardized counseling protocols (see Appendices E and F).[6]

> The use of the Web as a source for multi-infection information encouraged the counselors to investigate further independently.[6]

Training consisted of a number of components:[6]

- **Role plays, discussion, and other exercises.** Training on the experimental counseling protocol included counselors' reading the protocols and asking questions for clarification. They then used role-playing to practice and become familiar with the flow and structure of the protocols. Discussion, feedback, and problem-solving exercises helped to further familiarize counselors with the protocols. The trainers observed the role-plays and exercises, assisted counselors in brainstorming solutions to problems, and helped them further explore patient issues in the context of the protocols.
- **Cheat sheets.** Breakdowns of the protocol components and subcategories were provided for each of the sessions to help counselors follow the protocol as closely as possible.
- **Shadowing.** Newly hired counselors also shadowed trained counselors during counseling sessions (both intervention and control), and were encouraged to ask questions regarding both the session and the counselors' own experiences.
- **Educational materials.** Although the counselors were experienced and knowledgeable about HIV education, the multi-infection intervention required that they learn about STDs and hepatitis. The counselors were given articles from scientific journals and information sheets written in lay language, and these were discussed at weekly meetings. These materials consisted of both photocopies and Web-based literature and were also appropriate for use as handouts to study participants.

Data Collection

HIV, STD, and Hepatitis Testing

At the beginning (baseline) and end of the study period (six months), specimens were collected from both the experimental and control groups to test for HIV, hepatitis B and C, gonorrhea (urethral and pharyngeal), and chlamydia. At baseline, all participants were informed of results from the HIV tests, and those in the experimental arm received results from tests for STDs and hepatitis. Samples (blood, urine, and oral swab) were collected from control participants to be stored, frozen, until the end of the study. At that point, they were to be analyzed for STD and hepatitis infection to provide baseline data for the control arm.* All participants received results from a second set of tests for HIV, STDs, and hepatitis B and C at their six-month follow-up appointment.

A review of medical records was conducted for participants who reported previous diagnosis or treatment of an STD. Information on treatment, laboratory tests, and partner referral was collected for each incident.

Counseling and Testing Schedule

- Week 1 (Visit A): Informed consent and enrollment, baseline interview, randomization, pretest counseling, sample collection
- Week 2 (Visit B): HIV results disclosure, post-test counseling, referrals. STD and hepatitis disclosure for experimental arm only
- Week 2 or 3 (Visit C): Supportive post-test counseling session for any new positive test (experimental arm only)
- Week 6 (Visit D): Enhanced counseling session (experimental arm only)
- Week 12 (Visit E): Three-month follow-up interview
- Week 18 (Visit F): Telephone check-in
- Week 24 (Visit G): Six-month exit interview and second set of tests.

*During the study, urine and oral swab specimens from 72 of the control participants were lost by the Clinical Laboratories at SFGH.[8]

Surveys

Research staff administered surveys at baseline (Appendix G) and at six months (Appendix H), prior to the testing session. The interviews collected data on socio-demographics, general health and medical history, sexual behaviors, and injection drug use and practices. Sexual behavior data included number and type of sex partners, types of sex practiced, risk history of partners, and condom use practices. Injection behavior data included number of injecting and sharing partners, risk history of sharing partners, equipment sharing practices, and sterile equipment use. The interviews lasted approximately 60 minutes.

The Interventions

The multi-infection (experimental) and standard (control) C&T followed a similar schedule (see the Counseling and Testing Schedule sidebar), but the experimental condition included more counseling sessions. As discussed above, the control arm also did not include the same range of testing and treatment as the experimental condition. However, referrals for those services were provided. The sections that follow outline the two interventions in greater detail.

Multi-Infection C&T

Counseling

The experimental multi-infection counseling consisted of either three or four counseling sessions (see Appendix E), depending on test results:

- Pretest (week 1, baseline)
- Multi-infection results disclosure (week 2)
- Supportive post-test counseling session for any new positive test (week 2 or 3)
- Enhanced counseling session (week 6)

> The research team "intentionally avoided an 'infectious diseases 101' counseling session, as education alone has not been shown to be an effective prevention tactic."[8]

Table 1 compares the components of the pretest counseling for the experimental and control arms side by side (for further details, refer to the protocols in Appendices E and F). The multi-infection counseling "focused on the commonalities of transmission routes and the interrelationships between these infections."[8] For example, in the first session the counselor linked the participant's self-identified HIV risk behaviors to the risk of contacting an STD and hepatitis B or C, and described the increased risk that accompanies co-infection.

In the second and subsequent sessions, the content of individual counseling sessions was tailored to the individual's test results in terms of risk reduction as well as treatment, coping, referrals, etc., as appropriate. Risk reduction plans were a particular focus, and counselors provided reinforcement and worked with participants to revise their plans throughout the counseling series to increase their effectiveness.

Counselors kept detailed notes (Appendix I) on each participant's progress, including risk behaviors, test results, emotional reaction to results, referrals and medical follow-up, risk reduction and coping plans, and partner referral.*

Table 1 Pretest Counseling, Control vs. Experimental

Standard HIV C&T Components (Control) Time = 20–30 minutes	Multi-Infection Counseling Components (Experimental) Time = 20–30 minutes
Introductions and overview: Make emotional contact and outline the counseling session.	**Introductions and overview:** Make emotional contact and outline the counseling session.
HIV testing history and knowledge of HIV transmission: Explore prior test history and knowledge of HIV transmission.	**Risk assessment and risk pattern:** Explore HIV risk behavior, specific incidents, and risk pattern.
Risk assessment and risk pattern: Examine patient risk profile and prior risk reduction.	**Previous risk reduction and social influences:** Review previous attempts at reducing risk and explore social influences.
Self-perception of risk: Explore self-perception of risk.	**Self-perception of risk:** Explore self-perception of risk.
Risk synthesis: Synthesize and reflect back HIV risk profile.	**HIV risk synthesis:** Synthesize risk pattern and self-perception of risk.
Risk reduction education: Provide educational information on safer sex and safer injection practices.	**Multi-infection risk synthesis and integration:** Integrate risk of multi-infections into HIV risk behavior.
Risk reduction plan: Negotiate a risk reduction plan.	**Risk reduction plan:** Negotiate an incremental risk reduction plan.
Referrals: Make necessary referrals	**Referrals:** Make necessary referrals
Closure: Schedule follow-up and review contact info.	**Closure:** Schedule follow-up and review contact info.

*To ensure confidentiality, participants were identified only by their assigned ID number on all forms. See the Risks and Confidentiality section.

Testing, Treatment, and Referrals

As described in the Data Collection section, participants in the experimental arm were tested at baseline for STDs (gonorrhea and chlamydia) and hepatitis B and C, as well as for HIV. Treatment and/or referrals appropriate to the test results were then offered. Established reporting procedures were followed for all diagnosed cases of gonorrhea, chlamydia, and hepatitis B and C, since these are all reportable infections in California.

- Those testing positive for an STD were treated according to standard guidelines. They were also counseled on the importance of notifying their sexual partner(s), offered antibiotics for each partner identified, and instructed on their use. They were then referred to their primary care physician for follow-up.
- Participants who were found eligible for hepatitis A and B immunizations after screening were offered free vaccinations, to be administered at the study's C&T sites according to standard guidelines.
- Participants testing positive for hepatitis C or chronic hepatitis B were referred to their primary care physician or the SFGH Liver Clinic.
- Referrals for drug treatment, shelter, food, and public assistance were made as appropriate.

Control Arm

In addition to participating in the baseline and follow-up surveys (see Appendices G and H), participants in the control arm received brief, client-centered HIV prevention counseling and testing (see Appendix F). The two-session C&T was modeled on the CDC's recommended counseling for HIV test sites and public clinics.* The first session explored the participant's perception of risk, discussed the most recent risk incident, reviewed previous efforts toward risk reduction, placed the recent incident within a larger risk pattern, formulated a risk-reduction plan, and identified social support networks and referrals (see Table 1 and Appendix F).

After this counseling, specimens were collected for testing (see Data Collection, above), and expedited referrals were then provided for STD and hepatitis screening and vaccination, as described above in the Risks and Confidentiality section.

The second counseling session occurred the following week and included disclosure of HIV test results and post-test counseling. Appropriate referrals were made for HIV-positive test results, and additional brief counseling (in 5–7 days) was available for those who wanted it. Referrals for STD and hepatitis screening were repeated for those who had not yet followed up on the initial referral.

Participants returned six months later for the follow-up interview (see Appendix H). At that point they also received multi-infection counseling (see Appendix F); testing for HIV, gonorrhea, chlamydia, hepatitis B and C; and vaccination for hepatitis A and B, if desired. Those who began the hepatitis B immunization series were tracked for an additional six months in an effort to ensure completion of the series.

RESEARCH FINDINGS

Table 2 provides demographic data for the intervention and control groups. About three-fourths of the participants were male. The large majority were either white or black. The average participant age was 41 for the experimental group and 42 for the control group.

Table 3 shows baseline risk behavior data for both groups. About one-third had shared needles in the past 30 days, and 7–8% had an STD in the past 12 months.

Figure 1 provides information on participant retention over the duration of the study. Retention for the two groups was very similar, and there were considerable losses at the very last step—the test disclosures at the end of the six-month period.

The researchers did not detect differences between the two study groups with regard to behaviors or disease outcomes. There were however, several important key learnings that came out of the collaborative process. See the Lessons Learned sidebar, below.

COLLABORATION

Although both UCSF and the San Francisco Department of Public Health (SFDPH) have long been associated with San Francisco General Hospital (SFGH), of which HAPS is a part, none of the parties directly involved had prior experience with community collaborative research. Consequently, the partners faced the challenges of building both processes and working relationships from the ground up. The sections that follow describe the collaborators and the process they followed in working together. Their recommendations for others planning such a collaboration are presented following this section.

Collaborative Partners

HIV Assessment and Prevention Services (HAPS), San Francisco General Hospital

HAPS, part of the Epidemiology and Prevention Interventions Center (EPI-Center), provides clinical services, teaching, and research concerned with preventing and controlling infections among patients and health care providers at SFGH. HAPS has provided routine, confidential HIV testing and client-centered testing since 1993.

In the year prior to the study, HAPS served 1,110 clients with a staff of three full-time HIV counselors, a part-time

*See *HIV Counseling, Testing and Referral Standards and Guidelines.* U.S. Department of Health and Human Services, Centers for Disease Control and Prevention (1994).

KEY RESULTS

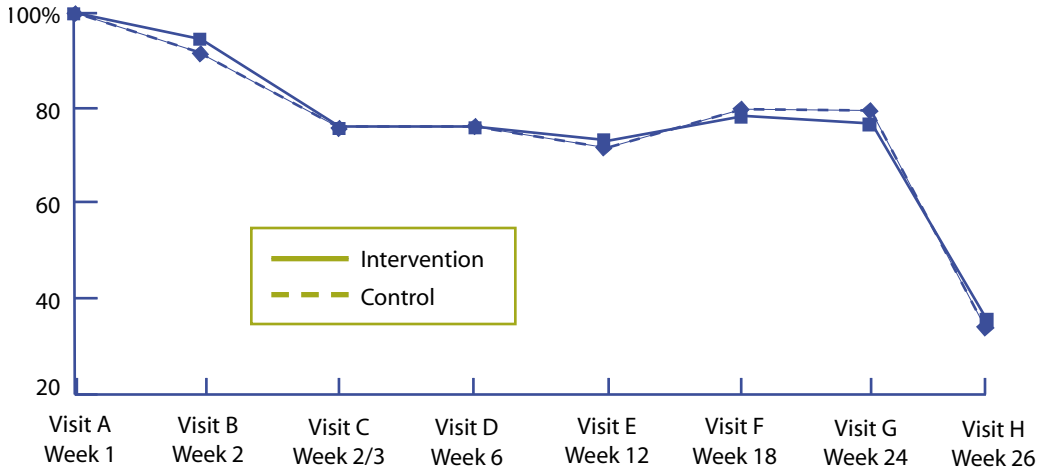
Table 2 Participant Demographics

	Intervention N = 108	Control N = 113
Sex		
Male	75.0%	74.3%
Female	25.0%	24.8%
Race/Ethnicity		
White	44.4%	45.1%
Black	36.1%	42.5%
Latino	14.8%	7.1%
Asian/Pacific Islander	1.8%	4.4%
Native American	–	0.9%
Mixed	3.0%	–
Age		
Mean	41.0	41.7
Range	18–70	21–57

Table 3 Risk Behaviors at Baseline

	Intervention N = 108	Control N = 113
IDU and used someone else's syringe in last 30 days	32.4%	39.8%
Anal sex within last 3 months	16.7%	14.2%
More than 1 heterosexual sex partner within last 3 months	63.0%	65.5%
STD within last 12 months	8.3%	7.1%

Figure 1 Participant Attrition



Note: Only experimental participants with a positive test result received the third counseling session (Visit C). Visits D and E were not part of the control condition T&C. Visit H was test results only.

Lessons Learned[8]

- CBO staff should be fully involved from the very beginning of the project in order to ensure equal participation between the partners and build their commitment to the project.
- Communication between partners needs to flow in both directions and be formalized as to type, form, and schedule in order to establish mutual trust and respect.
- Establishing standardized training methods benefits both the study as a whole and new staff that join the project midway due to staff turnover at the CBO.
- Adequate training time and resources must be allotted, especially when CBO staff need to assimilate a large amount of new information.
- Whenever possible, peer-based training should be organized in such a way that no single individual is overburdened.
- In collaborative studies between academic and CBO partners, at least one of the partners should have prior experience with collaborative research.
- For a CBO that is new to research, participation in a randomized, controlled trial is a substantial challenge.

program manager, and a volunteer medical director. The HAPS client population at the time was 22% homeless, 25% IDU, 12% MSM, and 65% people of color.

David Bangsberg, the HAPS director and an assistant professor of medicine at UCSF, was one of the two principal investigators for the project.

San Francisco Department of Public Health

The SFDPH has responsibility for assessing and researching the health of the community; developing and enforcing health policy; preventing disease and injury; educating the public and training health care providers; providing quality, comprehensive, culturally proficient health services; and ensuring access to these services.

The Community Health Network division of the SFDPH is San Francisco's health system and operates at locations throughout the city including San Francisco General Hospital Medical Center and more than 15 other health centers.

Jeffrey Klausner, director of the STD Program at SFDPH and an assistant professor of medicine at UCSF, was a principal investigator for the project.

University of California, San Francisco

UCSF, a public health sciences university, is one of the world's leading biomedical research and health science education centers. The creation of new scientific knowledge and making that knowledge broadly available through education and technology transfer are central to the university's mission.

Since its founding more than a century ago, UCSF has worked in partnership with the City of San Francisco to advance medical science and provide health care for the local community through San Francisco General Hospital. It is also affiliated with a number of other medical centers across the city. As of 2004, UCSF ranked fourth nationally in National Institutes of Health funding.

Edwin Charlebois, assistant professor of medicine at UCSF, briefly succeeded Dr. Bangsberg as a principal investigator in the latter stages of the study. Paula Lum, Center for AIDS Prevention Studies (CAPS), UCSF, was a co-investigator on the project and was responsible for training counselors on the study protocols.

Processes and Key Components of Collaboration

On-site personnel for the Take5! study included two research assistants, an academic social worker (MSW), an MD who also has a master's degree in public health (MPH), and the entire staff of HAPS (three counselors, the program manager, and the medical director). Staff from the SFDPH also were peripherally involved. The respective responsibilities and collaborative tasks are described below.

Protocol Development

The MSW had previously developed counseling protocols for the RESPECT[5] and Post-Exposure Prophylaxis studies, both of which integrated HIV C&T with screening for other bloodborne infections. Using these protocols as a foundation, the MSW began to develop the multi-infection counseling protocol. At weekly meetings, the HAPS counselors gave the MSW feedback on this model from the perspective of their first-hand experience with HIV C&T. Role-playing exercises were also used to test and refine the protocol in simulated "real-life" situations. The progress of protocol development was also discussed at another weekly staff meeting not attended by the MSW, with the counselors later relaying suggestions from other Take5! staff to the MSW.

The MSW then took the role-play results and other feedback and incorporated it all into a revised version of the

protocol, at which point the protocol was again presented to the counselors for testing, feedback, and review. Although the MSW left the project early on, this feedback-revision process between the counselors and researchers continued throughout the study, which allowed the input and experience of community-based staff to be fully incorporated. The revision process focused on the *approaches* used in the counseling sessions, thus allowing the integrity of the intervention to remain intact throughout the study.

Ongoing Communications

Weekly meetings provided the primary means of communication between the academic team members and the HAPS team members. The absence of the MSW at certain meetings allowed the counselors to speak freely about the challenges of the development process and solicit advice from others not directly involved in the process. In addition to protocol development, the team also discussed the importance from a research perspective of adhering to protocol guidelines. As much as possible, these meetings were held at the same time and place every week.

Training

Initially, because the counselors had helped develop the protocol, the only training needed was to convey background information on STDs, hepatitis, and co-infection/transmission. In the beginning of the project, educational materials were supplemented by visits from Department of Public Health personnel, who discussed STD counseling, answered questions, and distributed literature. In the later stages of the project, as staff turnover occurred, training was handled by the MD/MPH and the other counselors, as described in the Training section, earlier in this module.

Data Collection and Follow-Up

The academic research assistants were responsible for all participant interviews and most of the participant tracking. To avoid the possibility of a counselor-client type of relationship forming between interviewer and participant, the counselor (not the research assistant) generally escorted the client to have specimens collected for testing. On busy days or with clients from whom it was difficult to collect specimens, such as long-term IDUs, interviewers sometimes undertook this responsibility. Counselors handled follow-up calls to clients for scheduling counseling appointments, but not for other types of visits.

Counseling

All counseling was delivered by HAPS counselors. To avoid a potential for counselor bias, assignments to control and intervention counseling were rotated, sometimes with monthly assignments and sometimes by assigning every other patient to a different counselor, regardless of group assignment. Prior to scheduled testing, the counselors would agree on which assignment method would be used.[6]

Data Analysis

The academic members of the team were responsible for data aggregation and analyses.

RECOMMENDATIONS

The experiences of the partners in the Take5! study suggest some guidelines for those considering similar future collaborative research:[6]

- **At least one team member should have collaborative research experience.** To ensure a successful collaboration, at least one team member should have previous experience with an academic-CBO study. Such knowledge is a highly valuable resource and can help in addressing challenges and transferring skills from academics to CBO staff.
- **Acknowledge and plan for differences.** Academic researchers and CBO management and staff had differing perspectives and priorities. Anticipation of these differences early on makes it easier to identify and overcome them when they later arise. An increasing amount of literature on collaborative research is now available, and much of it is written in accessible, non-academic language. It is useful for the partners to discuss the challenges before development of the research protocol (for example) to establish a common understanding of the possible areas of conflict and to foster open communication about expectations, reservations, and possible solutions.
- **Engage CBO staff in the development process.** In order to establish respect and trust, build an equal partnership, gain the CBO staff's buy-in, and promote capacity building, it is important to involve front-line staff in both developing and *writing* the intervention protocol. This ensures that the language used is both understandable and comfortable to those using the protocol.
- **Distribute the responsibility for training.** In the beginning, the academic partners should handle training, in part to help establish them as a resource. As staff members gain experience, they develop the capacity to transfer skills and knowledge to new co-workers. Also, training on various aspects of the intervention can be assigned to those most interested in or knowledgeable about that topic, and can be rotated among staff to broaden their expertise and keep everyone engaged and interested.
- **Remain flexible on procedures and responsibilities.** Making flexibility a core principle of the project will help the

> "Capacity building must be an integral component of the design and goals of collaborative research if the full potential of the project is to be realized."[6]

team deal with unexpected events and changing dynamics, foster communication and trust, and help the project fit into the logistical life of the CBO.

- **Ensure that information flows in both directions.** To ensure that the partnership is truly equal and to foster mutual trust and respect, communication must be bi-directional. Also, it is important that the information flow be formalized as to type, mode, and frequency. Memoranda, emails, meetings, trainings, and supervision are examples of types of communication that should be employed. Collectively deciding when and how to communicate also supports team building. Team meetings—especially if they are prioritized and occur regularly and frequently—provide a productive setting for communication and improved collaboration.
- **Make capacity building integral to the study.** When a goal of the collaborative is to augment the skills and knowledge of both the academic and CBO team members, "a framework for capacity building must be merged with the methods of collaborative research."[6] This strengthens the collaboration by helping to establish respect and trust, and it adds meaning to the project outcomes. Kotellos et al. have proposed one such framework for evaluating organizational development in HIV prevention programs.*
- **Prepare for changing dynamics.** As the study progresses, leadership needs to shift back and forth between the partners. In the early stages of protocol and procedural development, leadership between the academic and CBO sides of the collaboration should be equal. During the implementation phase, the CBO will take the lead, with the academic researchers serving as essential resources. Finally, the research side assumes responsibility for the evaluation and data analysis. However, interpretation of findings should be a joint effort. Anticipation and planning for these transitions is imperative to the success of collaborative research.

CONCLUSION

This collaborative research project between USCF and San Francisco General Hospital's Assessment and Prevention Services arose from the need to develop comprehensive, "one-stop-shop" services for hard-to-reach populations. The researchers and intervention staff believed that if standard HIV testing and counseling protocols were expanded to include STD screening and treatment, high-risk populations would access these services all at once, rather than having to seek HIV and STD services in different clinical settings. This type of "multi-infection" approach provides opportunities to introduce risk-reduction messages, raise awareness, and fully engage individuals in hard-to-reach populations in testing and counseling for both HIV and STDs.

For a number of years, community-based organizations have advocated for policy to link funding streams for HIV/AIDS prevention and STD screening and treatment, in order to strengthen prevention programming targeting high-risk groups. This intervention study was an attempt at providing efficacy data that would support this goal. Although the study did not meet this aim, it did provide a number of recommendations and lessons learned for community-based research collaborations, including strategies for capacity building, protocol development, and recruitment strategies for high-risk populations.

*See K. Kotellos, J. Amon, and W. Benazerga, "Field Experiences: Measuring Capacity Building Efforts in HIV/AIDS Prevention Programmes," *AIDS* 12, suppl. 2 (1998): S109–S117.

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Appendices

ABOUT THE MODULE 9 APPENDICES

These appendices contain tools that can be used to:

- Collect data on medical history, multi-infection risk behaviors, and condom use intentions
- Track research participants' likely whereabouts in order to maintain contact and locate for follow-up activities over the term of a longitudinal study
- Support training for HIV test counselors to work in a multi-infection C&T setting

Sample materials in the appendices include:

- Screener and consent forms
- Forms and protocol used in tracking research participants
- Protocols for multi-infection (STDs and HIV) intervention counseling sessions
- Baseline and follow-up surveys

Each of the appendices is described briefly below.

Appendix A. Screener Form

This form is used to ensure that participants meet the research study's eligibility criteria.

Appendix B. Consent Form

Participants sign this form to affirm that they have been informed of the risks and benefits of participation in the study. It describes their rights and the study's background, purpose, and procedures, as well as its benefits (including incentive payments) and potential risks and discomforts to subjects.

Appendix C. Contact Information Form

In order to maintain contact with participants over the course of the six-month study period, contact information was collected at each visit. This information includes permanent address (when possible), alternative contacts (friends and relatives), and other ways to locate the individual. Any use of community services—such as shelters, free meal programs, drug treatment programs, and needle exchanges—is also recorded as a potential means of locating participants.

Appendix D. Tracking Protocol

This one-page document describes the procedure for using the information collected on the Contact Information form (Appendix C) to locate participants who missed appointments, as well as what to do should the contact information prove insufficient.

Appendix E. Intervention Counseling Protocols

This appendix provides scripts and instructions for each of the experimental intervention's counseling sessions, including different versions for varying test results (positive versus negative) for the diseases tested for. Counselor resources for additional information on STDs and referrals are also included.

Appendix F. Control Counseling Protocols

This appendix provides scripts and instructions for each of the control condition counseling sessions, including different versions for varying HIV test results at Visit B and, for the final visit, all the diseases tested for.

Appendix G. Baseline Surveys

The baseline instrument was administered to both control and experimental participants at the first visit. It collects sociodemographic data, medical history, and detailed information on sexual behavior and use of drugs and alcohol.

Note: Different versions of the survey were used for male and female subjects. Only the male version is reproduced in the printed version of this module. Both the male and female versions are available for download from the UARP web site as Microsoft Word files; go to **http://uarp.ucop.edu/ca_collaborations/modules/module9a_app.html.**

Appendix H. Follow-Up Surveys

The follow-up instrument was administered to both control and experimental participants at six months, just prior to the final testing session. It collects the same information as the baseline survey (see Appendix G), but focuses on the last three months.

Note: Different versions of the survey were used for male and female subjects. Only the male version is reproduced

in the printed version of this module. Both the male and female versions are available for download from the UARP web site as Microsoft Word files; go to **http://uarp.ucop.edu/ca_collaborations/modules/module9a_app.html.**

Appendix I. Progress Notes Forms

These forms collect test results data, referral information, and counselors' observations about client perceptions, reaction to results, planned course of action, changes in behavior, and the like. Where appropriate, different forms are provided for experimental and control subjects.

Use of Materials

All the resources presented in the appendices for Module 9 are derived from materials developed and used as part of the project listed below. These materials may be freely used for HIV/AIDS prevention intervention evaluation programs. Publications that use any of the forms, surveys, and so forth, or that are based on any of the materials included in these appendices, should provide a citation of the original project and principal investigators:

A Randomized Controlled Trial of a Multi-Infection Counseling and Testing Intervention Compared to Standard HIV Counseling and Testing to Reduce HIV-Related Behavior Among High-Risk Populations in San Francisco, California

UARP grants PE99-SF-3174 and PE99-SF-3175

Principal investigators:
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Edwin Charlebois, Department of Medicine, UCSF
Paula Lum, Center for AIDS Prevention Studies, UCSF