

# Research Portfolio

Center for AIDS Prevention Studies (CAPS)

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## HEPCAP: Hepatitis C in the California Prisons Project

Project Staff: Dr. Kimberly Page-Shafer, Principal Investigator, Drs. Steve Morin, Teresa Wright and Michael Busch, Co-Investigators. Project Staff: Dr. Nancy Moss, Sue Currie, Alison Canchola, Joyce Balls.

Project Description: This is a study of hepatitis C virus (HCV) infection in the California State Correctional System that began in December, 2000. This comprehensive multi-site investigation includes epidemiological, clinical and policy studies. This investigation:

- studies the risk of prevalent and incident (newly acquired) hepatitis C infection in California prisons for both inmates and employees
- evaluates HCV treatment candidacy and response among those who are enrolled in the study
- prevention procedures in infection control and safety procedures in order to protect correctional officers and uninfected inmates from blood-borne pathogens, including HCV, HBV and HAV.

Significance: Epidemiological data shows that over 40% of inmates entering California Prisons are infected with HCV. It is believed that the majority of these infections occur before incarceration. However, correctional facilities may also represent a high-risk environment for HCV infection because of the combination of a high prevalence among this population and their continued use of drugs and tattooing. It is possible that sexual activities may also play a role in the transmission of HCV among prison populations. The rate of new infections and the risk of transmission of HCV that may be occurring in California prisons is unknown. Due to exposures to various body fluids, including blood, correctional personnel, particularly enforcement officers and medical technicians, may be at increased risk of HCV from the inmate population. Until now, this study would have been extremely difficult and cumbersome to undertake due to the high cost of enrolling large cohorts and following them prospectively. Our group will be using biomedical strategies that will allow for the detection of new or incident cases of HCV, facilitating a unique one-time study of HCV infection and associated risk. As well, this project will, for the first time ever, provide an accurate knowledge base for the prevention of HCV in correctional institutions and the implementation of treatment, education, policies and procedures—for both inmates and staff persons—in the California State Correctional System.



## HIV Superinfection among Seroconcordant Couples

Project Staff: Greg Greenwood, Jeff McConnell, & Robert Grant

**Project Description:** The question of whether an individual who is infected with one variant of HIV-1 can be re-infected with a second variant of HIV-1 has been posed since promising HIV treatments became available. Regrettably, we still do not know the answer to this question. We seek to establish the feasibility of a study of HIV superinfection by enrolling 50 HIV positive couples (male-male, female-female, male-female, and male-transgender) in a one-year cohort study. We hope to demonstrate that virological assays can identify couples whose viral strains are readily distinguishable at baseline. These data will then be used to support an R01 proposal to the National Institute of Health, or a proposal to the Center for Disease Control and Prevention to conduct the full study (200+ seroconcordant couples). The primary, long-term aim is to determine if a person who is infected with one variant of HIV-1 can be re-infected with a second variant of HIV-1 that is drug resistant. If HIV superinfection occurs, secondary aims are to determine the frequency of such transmission, and to identify its medical, behavioral, relational, and attitudinal cofactor effects.

**Significance:** Knowing whether or not HIV superinfection occurs, and how often, has serious implications. If it does *not* occur, it would be good news for HIV-positive couples who enjoy unprotected intercourse with each other, who want to have children, or who need organ transplantation from HIV-positive donors. It would also provide a scientific basis for public health officials and physicians to counsel seroconcordant couples about the risks of unprotected intercourse. If superinfection *does* occur, risk reduction protocols could clearly outline the risks for HIV-positive couples to make more informed decisions about their sexual practices. Additionally, HIV superinfection might worsen disease progression or complicate treatment in other ways, or could provide additional obstacles in HIV vaccine development.

**Interesting Findings:** With the aid of a diverse and dedicated Community Advisory Board (CAB) consisting of 20+ HIV-positive community members and HIV providers from the San Francisco Bay Area, we built the research infrastructure to start the pilot study. From mid-December 2000 to early February 2001, we recruited and enrolled 10 pilot couples. Preliminary analysis of the behavioral and virological data on eight of these couples suggest that this design will return a sample well suited to the study of HIV-1 superinfection, and that these data will contribute to the exploration of the superinfection question from early on in the data collection process.



## The HEYMAN Project: A Survey of HIV Seroprevalence, Markers for Hepatitis and Sexually Transmitted Diseases, and Assessment of Associated Risk Behaviors in Young Men Residing in Low-Income Neighbourhoods in Five Northern California Counties

Project Staff: Juan Ruiz (California DHS -Office of AIDS), Kimberly Page-Shafer, Matthew Facer, George Lemp, Jeffrey Klausner, Fred Molitor, Barbara Allen, Geneva Bell-Sanford, William McFarland, Scott Morrow

Project Description: The HEYMAN Study is a sequel to the Young Women's Survey (YWS) which was conducted between the period of 1996-1998. Just like YWS, HEYMAN is a collaboration of the California Department of Health Services, Office of AIDS and Center for AIDS Prevention Studies.

HEYMAN will be conducting a survey of young men, aged 18 to 35 years, who live in San Francisco Bay Area low-income neighborhoods (where the median household income estimated from the 1990 U.S. Census was below \$15,000). These neighborhoods will be selected from the counties of Alameda, Contra Costa, San Francisco, San Joaquin, and San Mateo. The study will be conducted through to September 30, 2003 and approximately 500 participants at each of the five proposed sites (for a total of 2,500 participants) will be recruited.

The purpose of this survey is to estimate prevalence and risk factors for HIV infection and sexually transmitted diseases such as syphilis, chlamydia, gonorrhea, herpes, and hepatitis A, B, and C. The sample of 2,500 young men will be recruited from households in selected low-income neighborhoods. This survey will also collect a blood sample and information regarding sexual activity, drug-use, needle-sharing behaviors and other factors that may place young men at increased risk for infection with HIV.

Significance: The HEYMAN study provides a means not only to monitor the HIV epidemic but to provide risk behavior data and prevalence information on young men in low-income neighborhoods. This information will be used to improve health programs for young men in these areas and to target and develop better methods of helping young men prevent disease and promote good health.



## HOT Study: Oral Transmission of HIV

Project Staff: Principal Investigator: Dr. Kimberly Page-Shafer; Co-investigators: Drs. Caroline Shiboski, Dennis Osmond, Deborah Greenspan, James Dilley, and William McFarland. Project Staff: Joyce Balls (CAPS), Daniel Tracy and Shannon Casey (AIDS Health Project), and Behnaz Cheick (Oral AIDS Center)

Project Description: The HOT Study is investigating whether oral health, oral hygiene practices, different oral sex practices and/or drug use influences whether a person can acquire HIV virus orally. The HOT study is being conducted over a five year period, which includes four years of data collection. The study will be conducted in the San Francisco Bay area in collaboration with the AIDS Health Project. Subject recruitment will consist of 80 Case Individuals (those individuals who acquired HIV via oral transmission) and 320 Control Individuals (corresponding in gender and location, with similar risk factors but who have not acquired HIV). Each respondent will receive free HIV testing, oral exams by an oral health professional and behavioral/clinical questionnaires. Specific project aims:

1. To evaluate if host oral environment including signs and symptoms or periodontal disease, and/or health practices are associated with increased odds of oral acquisition of HIV infection.
2. To evaluate which specific orogenital sexual practices and oral exposure to ejaculatory fluids (including swallowing and not swallowing semen) are associated with increased or decreased odds of oral acquisition of HIV.
3. To evaluate if documented comorbid conditions within the seroconversion period (for instance- sexually transmitted disease such as gonorrhea, chlamydia and other viral infections like HSV-1 or 2) are associated with increased or decreased odds of oral acquisition of HIV.
4. To evaluate whether non-injecting substance use which may modify the oral or naso-pharyngeal mucosa and or sexual behavior is associated with increased or decreased odds of oral acquisition of HIV.

Significance: This study is the only one of its kind! The design and methods are aimed at really giving us the information we want to establish how someone might get HIV infection from performing oral sex. The case-control method cannot estimate infectivity or the rate of oral HIV infection, but it is the only feasible way to study factors which may influence the risk of oral infection. Identification of the cofactors possibly associated with orogenital HIV acquisition will provide the kind of data that can be used by AIDS prevention programs and members of AIDS risk groups in order to reduce the risk of HIV infection.



## Primary HIV Infection: Epidemiology and Prevention and Immunologic and Virologic Features of Early HIV Infection (Options Project)

Project Staff: Frederick Hecht (PI), Jay Levy (PI), Margaret Chesney (Co-PI)

**Project Description:** The objective is to identify people when they are early in HIV-infection, provide them with the option of HIV treatment regimens and counsel them on adherence and coping with the stress of HIV infection. We are hoping to see if early treatment of HIV will reduce disease progression and that counseling will reduce risky behavior. We are also examining the prevalence of drug resistant HIV strains among newly infected persons and formulate new strategies to estimate the date of HIV infection.

**Significance:** The study has become one of the most successful efforts in the world to identify persons recently infected with HIV. The study has provided the first published documentation of sexual transmission of protease inhibitor resistant HIV (*New England Journal of Medicine*, July 30, 1998). On-going studies of transmission of drug resistant virus provides a key sentinel role for monitoring the potential emergence of multi-drug resistant HIV transmission. Careful documentation of the mode of HIV transmission, which is made possible by finding persons close to the time of transmission, is permitting better definition of the role of oral sex transmission in current transmission of HIV. The finding that even with state-of-the-art HIV test counseling, a significant number of recently infected persons continue to engage in high risk behavior that may infect others identifies a key issue for HIV prevention efforts. Further information from the study is expected to provide important data that may help to target more effective risk reduction efforts to those most likely to have continued risk behavior.

### Interesting Findings:

- Patients with primary infection achieve higher CD4 cell counts when IL-2 is added to HAART.
- There is evidence of improved maintenance of CD8+ noncytotoxic cell suppression of HIV-1 in patients receiving IL-2 although further study is needed.
- Use of the less sensitive (detuned) EIA testing strategy has been confirmed to be useful in documenting recent HIV infection in the study setting by expanding confirmation of recently infection status by 50%.
- Primary nucleoside and non-nucleoside reverse transcriptase inhibitors selected mutations were transmitted each time they were present in 4 pairs.
- All 10 secondary mutations in protease or reverse transcriptase we identified in source partners were transmitted.
- Although larger numbers of partner pairs are needed for more definitive analysis, our results thus far suggest that many HIV resistance mutations may be readily transmitted.
- Oral transmission represented 7.8% of primary HIV infections in MSM in this cohort and may be an important current mode of transmission in some MSM populations where unprotected anal sex has decreased, but unprotected oral sex is frequent.
- Standardized investigation of reported oral transmission is needed to better understand the epidemiology and risk of this behavior.
- Prevention strategies are needed that appropriately address the issue that unprotected oral sex is a lower risk than anal or vaginal sex, but still has risk of HIV transmission.



## The UFO Study – HIV and Hepatitis in Young Injectors: A Community Study

Project Staff: Dr. Andrew Moss, Principal Investigator, Drs. Kimberly Page-Shafer and Philippe Bourgois, Co-Investigator. Dr. Paula Lum, Medical Director, and Judith Hahn, M.A, Research Director. Project Staff: Peter Davidson, Ellen Stein, Jennifer Evans, and Bridget Prince.

**Project Description:** This NIDA-funded study is a prospective cohort study with an ethnographic component, to examine HIV and hepatitis B and hepatitis C infection in young injectors. The study is now screening young (under age 30) injection drug users (IDUs) in San Francisco and recruiting 300 of those who are seronegative for HCV into a prospective cohort study. The principal aim is to study risk factors for HCV seroconversion. We are also testing an accelerated schedule for vaccination against HBV, and using participant-observation ethnography methods to document the lifestyles and injecting practices of young injectors.

**Significance:** In our previous studies we found moderate HIV seroprevalence among young heterosexual injectors (2%), probably attributable to the widespread use of clean needles. Yet HCV seroprevalence was high (42%), and rose rapidly with age to 69% in those aged 25-29, among a population with high access to needle exchange. Thus, we hypothesized that sharing injecting equipment other than needles may transmit HCV, and are exploring risk factors such as sharing drug equipment used to dissolve drugs, such as cookers, cottons, and water, and the practice of backloading, used to divide drug solutions. We are using ethnographic methods to reveal how partnerships based on obtaining drugs, previously studied among older injectors, may have social benefits in addition to HCV risk for young IDUs. Additionally, we found in our previous work that only 13% of young IDUs in San Francisco had serological evidence of vaccination against HBV. This is a scandalous situation when an effective vaccine exists, and we are therefore testing a method of achieving rapid and persistent vaccine-mediated immunity to HBV in young IDUs.

**Interesting Findings:** Preliminary results of 122 young IDUs studied for a median of 9 months show that HCV incidence is high (22% ppy, 95% CI: 14-32% ppy). The most important risk factor for seroconversion was the social behavior of pooling money to buy drugs (RR=7.6 95% CI:1.7-33.2). Sharing drug preparation equipment (RR=4.6 95% CI: 1.5-14.3) and backloading (RR=3.2 95% CI: 1.1-9.2), which occurred frequently when money was pooled to buy drugs, were also associated with HCV seroconversion. Our ethnographic observations showed that there were clear economic and social reasons for pooling money to buy drugs, and injecting together was a social experience, "like having a beer together." Women who borrowed needles were also at very high risk for seroconversion (RR=18.6 95% CI: 2.1-164). Most women who borrowed needles borrowed from a sex partner and were injected by their sex partner. Ethnographic data showed that young women in sexual relationships often gained stability, drugs, and protection, yet had lack of control over the injection process. "Even after we first came out to San Francisco he still always copped [bought] the drugs and did everything. He wouldn't let me hit [inject] myself or even cook up the drugs. I only learned how to do everything when he went to jail."

These results show that HCV risk is a natural consequence of the social situations of street life and drug injection, and HCV prevention must take into account the social situations of young injectors. We recommend the involvement of current IDUs in the development of network-based interventions to reduce the risks associated with the social behavior of pooling money to buy drugs and subsequently preparing and injecting the drugs together, and to reduce the risk to young women IDUs in sexual relationships.



## Challenges in HIV/AIDS Treatment (CHAT)

Project Staff: G. Michael Crosby, Ph.D., M.P.H (Principal Investigator); Maria Ekstrand, Ph.D. (Co-Principal Investigator); Jeffrey R. Martin, M.D., M.P.H (Co-Investigator); David Bangsberg, M.D., M.P.H (Co-Investigator); Robert D. Webster, M.P.H (Project Director); Jay Paul, Ph.D. (Consultant); Kevin Sciecinski, B.B.A (Project Assistant); Sherry Fung, B.A. (Interviewer); Angel Gil, Medical Asst./E.M.T., (Phlebotomist/Interviewer); Ami Student, B.A. (Interviewer); Milam Freitag, Ph.D. (Counselor); Malka Wietman, M.F.T (Counselor); Mary Schroeder, B.A. (Counselor); and Nigel Reyes, A.A. (Recruiter).

Project Description: CHAT is a controlled, randomized trial of a behavioral intervention designed to increase HIV antiretroviral treatment adherence, thereby lowering HIV viral load levels among HIV positive individuals who use or abuse alcohol and/or drugs. The intervention, derived from Social Action Theory, consists of a series of six individual counseling sessions. The efficacy of the intervention will be tested by comparing the prevalence (and level of) detectable HIV viral loads in blood, level of CD4 counts in blood, and rates of self-reported adherence to antiretroviral treatment regimens in subjects of the regular treatment (control) and intervention arms. Those individuals living in the San Francisco Bay Area who are currently taking antiretroviral medications, who have a detectable viral load, and who use or abuse alcohol and/or drugs, specific to our screening requirements, are eligible for participation. The goal is to enroll 500 individuals from the San Francisco Bay Area.

Individuals who meet the study inclusion criteria are randomly assigned to either the intervention or control group. Intervention participants receive 6 one-on-one counseling sessions, utilizing a standard set of intervention "tools" tailored to individual needs, and motivational interviewing techniques. Participants are re-assessed at 4, 8 and 12 months.

We hypothesize that the intervention group will have a greater reduction in viral load, a greater increase in CD4 counts, and higher rates of self-reported adherence to antiretroviral treatment regimens at follow up compared to control group participants.

Significance: A number of HIV antiretroviral treatment failures are thought to result from the ability of HIV to develop drug resistant strains. The rapid reproduction rate of the virus, when not suppressed by medications, is thought to contribute greatly to the development of drug resistant strains. Adherence to triple combination therapies is highly complex, involving the use of approximately 20 pills per day under a variety of dietary restrictions. Alcoholic and substance users have long been characterized as non-adherent for other medication treatments (i.e., TB). Behavioral interventions that increase adherence of complicated regimens among those who have alcohol and/or drug problems must be developed and implemented community-wide.

Findings: Data collection began on 08/11/99 and will continue until 12/01/02. Presently, 218 individuals have been recruited for the baseline qualifying interview, 158 (72.5%) have been randomized. Baseline findings for the first 100 participants show that the mean age was 40 years, 91% were male, and 85% identified as homosexual. Eighty-nine percent reported some lifetime drug use, 24% reported drug use in the past 4 months, and 18% reported frequent/heavy drinking. At baseline, alcohol and drug use was associated with non-adherence to HIV-antiretroviral medication. Sexual risk taking was significantly related to identifying as "gay" ( $p < .005$ ) and to having sex while high on recreational drugs ( $p < .0001$ ). Compared to those who adhered, participants who reported missing at least 10% of their medications were more likely to report medication side-effects (60% vs. 40%,  $p < .08$ ), more likely to be angry ( $p < .07$ ), have less structured lives ( $p < .10$ ), and tended to have lower incomes ( $p < .09$ ).



## Accuracy of Self Reported Sexual Behavior among Female Adolescents

Project Staff: Nancy Padian, Alexandra Minnis

Project Description/Significance: Growing numbers of economically disadvantaged Latino and African-American adolescents in the San Francisco Bay Area face a range of health problems, particularly those related to reproductive health. Although the PI on this project, Dr. Padian, has been examining reproductive health outcomes and behaviors within these populations for several years, she has come to recognize that how such behaviors are assessed is critical. This project seeks to identify accurate and acceptable ways to measure high-risk sexual behavior among female adolescents, and, in particular, to examine how the willingness to report sensitive information may vary across data collection modes. Two hundred Latina and African-American female adolescents aged 15-19 will be recruited from New Generation Health Center, a teen health clinic located in San Francisco's Mission District. Reliable information is needed to inform the development of culturally and developmentally appropriate prevention programs and services that maximize the use of existing resources, as well as increase the capacity and capability of institutions to be more responsive to this segment of the population. The findings from this study will inform the research design of future projects in which Dr. Padian and other investigators in her department engage.

The specific aims of this project are:

- To evaluate the effects of data collection mode (audio computer-assisted self-interviewing (ACASI) vs. written self-administered questionnaire (SAQ)) on reporting of high-risk sexual behavior among African-American and Latina female adolescents aged 15-19 in San Francisco
- To compare the reliability of each interview mode by comparing reported behavioral risk of sexually transmitted infections with prevalent STIs diagnosed through urine-based testing.
- To assess the acceptability of computer-based interviewing among this urban adolescent population, and to explore the feasibility of its use at adolescent health clinics.
- To examine how the willingness to report sensitive information within each interview mode may be influenced by socioeconomic status, country of origin (e.g., Mexico vs. United States), and reproductive health history.



## Comparative Assessment of Slip-On Plastic Condoms and Latex Condoms

Project Staff: Nancy Padian, Phil Darney, Erin Loomis

**Project Description/Significance:** The primary objective of this clinical study is to evaluate the contraceptive effectiveness of the eZ-on® polyurethane condom compared to that of a latex condom marketed in the United States. The secondary objectives are to assess functionality (i.e., clinical breakage and complete slippage), as well as safety and acceptability of the condoms. The association between functionality of the condoms and pregnancy prevention also will be explored.

This is a single blind, comparative, prospective, parallel group, multicenter, randomized study. Couples will be randomized into either the eZ-on condom group or the latex condom group and instructed to use their assigned study condoms and no other method of contraception during each coital act over the study period. Each couple will use their assigned condoms for a period of 30 weeks to ensure that all clinically detectable pregnancies resulting from intercourse in the first six months of product use are detected. Also, as long as a woman's average menstrual cycle is 30 days or less, 30 weeks of condom use will allow sufficient time to complete six cycles of use and perform a pregnancy test six days after the end of the sixth cycle. The total duration of the study is the recruitment period plus at least 30 additional weeks after the last couple has been admitted.

This multicenter study will be conducted at nine research centers in the United States in at least 900 couples (450 per condom study group). Each center will attempt to enroll an equal number of couples. Family Health International, the study sponsor, will analyze study data.



## Measurement and Prediction of AIDS Risk Among Injecting Drug Users

Project Staff: David R. Gibson, Martin Young, Estie Hudes, David Donovan

Project Description: Objectives include assessment of reliability and validity of self-reported risk behavior; methods for improving the validity of self-reports; and examination of psychosocial predictors of sexual and injection-related risk behaviors.

Significance: In the absence of a gold standard for validating self-reported behaviors, we sought to model and correct for response bias in self-reports.

Interesting Findings: Self-reported sexual behaviors did not appear to be contaminated by socially desirable response tendency; however, self-reported injection risk behaviors appeared to be underreported due to social desirability. Modeling of response bias suggested that while 38% of the sample acknowledged sharing of syringes, upwards of 60% of the sample may have engaged in this practice.



## The Ryan White Prevention Project: Assessing Prevention Practices Among Ryan White CARE Act Providers

Project Staff: Stephen F. Morin, Principal Investigator, James O. Kahn, Co-Principal Investigator, Margaret Chesney, Co-Investigator, T. Anne Richards, Co-Investigator, Andre Maiorana, Project Director

**Project Description:** This project, funded by Health Resources and Services Administration (HRSA), is designed to assess the extent and variation of prevention practices for HIV-infected patients in a sample of clinics funded under the Ryan White CARE Act. The goal of this project is to better understand how clinical settings can be used to assist HIV-infected people to interrupt further transmission of HIV. The specific aims for this study are to assess: 1) the current practices of providers regarding prevention for HIV-infected patients in Ryan White funded primary care settings, 2) the incentives and barriers to providing prevention services for HIV-infected patients in these clinical settings, and 3) the perceptions of patients receiving care in these clinical settings regarding their prevention needs and the services provided.

This project will assess clinic prevention practices in eighteen primary care settings in nine US cities with varying AIDS incidences. This study involves four procedures: 1) exit surveys, 2) qualitative interviews, 3) ethnographic observations, and 4) secondary data analysis. 100 exit surveys will be conducted in each city to obtain information directly from patients receiving HIV care regarding their access to and utilization of HIV prevention services available through the clinic. One key clinic administrator, four health care providers, and four patients will be interviewed to determine how each evaluates prevention services and practices at the clinics. Observational field notes will take place at each site for availability of prevention materials such as posters, brochures, condoms and referrals for needle exchange. Secondary data to be reviewed will include the mission statement for the organization, populations served, guidelines and protocols related to prevention activities, and funding patterns in each location.

Primary prevention services for people living with HIV has emerged as a recent priority in HIV prevention research, due in part to the fact that more people with HIV are living longer and more sexually active lives. If prevention programs are to more effectively reach HIV-infected people, linking clinical care and prevention is the next logical step. Medical providers are in a very strategic position to help prevent transmission of HIV by assessing their patients for risky sexual and needle-sharing behaviors, and providing counseling or referrals to prevention services. The findings from this project will assist HRSA in deciding what approach to take to respond to the recent recommendations of the Institute of Medicine to provide more specific prevention services for HIV-infected individuals in primary care settings. We hope to be able to develop and evaluate model programs, and to contribute to the development of guidelines for primary prevention that could be incorporated into clinical standards of care.

We are finishing the pilot phase of this study in San Francisco at the Positive Health Program at San Francisco General Hospital and Clinica Esperanza at Mission Neighborhood Health Center. We are making the necessary changes to the quantitative instrument for the patient exit surveys, and analyzing the data from the qualitative interviews conducted for the pilot, as well as refining our sampling criteria before we start the full study in nine US cities.



## Study of the Consequences of the Protease Inhibitor Era (SCOPE)

Project Staff: Melissa Krone, M.S.

Project Description: A prospective cohort study dedicated to evaluating the long-term consequences of highly active antiretroviral therapy has been initiated. The Study of the Consequences of the Protease Inhibitor Era (SCOPE) will enroll 400 patients. Eligible patients must have a baseline CD4 T cell count > 50 cells/mm<sup>3</sup> and a nadir CD4 T cell count < 500 cells/mm<sup>3</sup>. Patient's treatment history must meet one of the following categories: (1) untreated (n=100): no antiretroviral therapy for the preceding 24 weeks; (2) virologic responders (n=100): stable combination therapy with a plasma HIV RNA < 50 during the preceding 24 weeks and (3) virologic non-responders (n=200): stable combination therapy with a plasma HIV RNA > 2500 copies/ml during the preceding 24 weeks. Patients are seen every four months where a detailed questionnaire is administered and plasma, serum, peripheral blood mononuclear cells, and saliva are obtained. Data is managed using a real-time web-based central data coordinating center.

Significance: The relationship between viral replication, CD4 T cell depletion and disease progression has been well described among untreated HIV-infected adults. However, the relationship between these factors has not been adequately described in the era of highly active therapy, especially in patients who fail to maintain durable suppression of viral replication. We have therefore established a prospective cohort study with two primary objectives: (1) to observe the long-term outcome of patients failing to achieve complete viral suppression with combination therapy and (2) to develop a specimen bank aimed at supporting biologic investigation of the factors associated with virologic, immunologic and clinical progression among treated patients.

Interesting Findings: The project is in its enrollment phase. During the first 4 months, 143 patients have been enrolled (120 male, 22 female, 1 transgender). The mean age is 45.7 years, and there is a diverse racial distribution (53% White; 24% African-American; 10% Latino; and 13% other). Of the 143 patients, 17 are treatment naïve or untreated, 52 are virologic responders and 74 are virologic non-responders.

## Acceptability of Diaphragm Use in Zimbabwe

Project Staff: *CAPS*: Nancy Padian, Ariane van der Straten, Judy Quan, Melanie LaPorte Smith;  
*Zimbabwe*: Tsungai Chipato, Gertrude Khumalo-Sakutukwa, Vicki Bunnnett

Project Description/Significance: In Zimbabwe, where it is recognised that male partners control sexual activity and decision-making and prefer “dry and tight” sex, the majority of women have found it very difficult to negotiate safe sex, particularly consistent condom use. Some of the reasons that have been cited for non-compliance with male condoms include decreased sensitivity and sensation and interruption of sex. Although the female condom has been recently marketed as an alternative barrier method, its efficacy is not yet known and still requires full consent and active co-operation of the male partner, is not reusable and therefore relatively expensive for ordinary women in developing countries. The diaphragm, on the other hand, is reusable, has low cost per use, can be inserted up to six hours before intercourse, can be left in place for 24 hours and it can be used without the knowledge of the partner. While male condoms are very effective at preventing unintended pregnancy, HIV and other STIs, a female-controlled method proven to prevent STIs and unintended pregnancy does not yet exist and thus, is urgently needed. If proven acceptable and efficacious as a female-controlled barrier method, the diaphragm would prove an excellent option for women who desire to reduce their risk of acquiring HIV, STIs and unintended pregnancy.

The specific aims of this project are:

- To evaluate the acceptability of the diaphragm among women who are at risk of unintended pregnancy, HIV, and other STDs;
- To examine compliance with and acceptability of diaphragms for contraception and disease prevention;
- To determine the feasibility and desirability of conducting a large intervention trial; to examine the effectiveness of diaphragms (with or without microbicide) in preventing HIV and other STDs in this study population with a high incidence of such infections.



## Compensated Sex among Adolescent Girls in Zimbabwe (In-School Girls)

Project Staff: *CAPS*: Nancy Padian, Ariane van der Straten, Judy Quan; *Zimbabwe*: Tsungai Chipato, Gertrude Khumalo-Sakutukwa, Megan Dunbar, Hazel Chinake

**Project Description/Significance:** The purpose of this proposal is to support pilot research activities in Zimbabwe necessary for the development of an intervention study for a future RO-1. The intervention will target adolescent girls (aged 15-18) who are engaging in, or who are at risk for engaging in, sex for economic necessities (compensated sex), including school fees and uniforms, living expenses, or other material goods. These girls are at particular risk for HIV, sexually transmitted infections (STIs) and unwanted pregnancies, as well as other adverse reproductive health outcomes. The intervention will consist of an economic strategy geared towards keeping adolescent females in schools, or helping school drop-out youth get back into school, coupled with a job-training program tailored to the development of marketable skills. In addition, we will train teachers in using strategies that reinforce and reward girl student achievement. Furthermore, we will implement an information, education and communication (IEC) program developed to address the "sugar daddy" phenomenon (described in greater detail below). This IEC program will be integrated into both the school and skills training components of the intervention. Finally, female students who graduate from school and skills-training programs will be provided with a small grant or loan to get them started in their next step, be it college, a job, or a business.

For the intervention, we will propose a randomized controlled design, in which secondary schools will be the unit of randomization, and school attendance and achievement, economic success, reported sexual behavior, incident STIs/HIV, and pregnancy will be the outcomes. Both intervention and control groups will receive the training and materials needed to implement the government sanctioned AIDS-prevention education curricula (described in Section B). Intervention groups will in addition receive the economic intervention, the IEC program, and enhanced teacher training emphasizing the academic achievement of girls. Participants will be followed for a minimum of three to a maximum of four years, including two years post-intervention. Outcomes will be measured through a behavioral questionnaire, school records, monitoring of business ventures and job performance, and diagnostic tests for HIV, STIs and pregnancy. Effects will be estimated to provide country-level as well as overall tests of the intervention on our outcomes of interest.



## Compensated Sex among Adolescent Girls in Zimbabwe (Out-of-School Girls)

Project Staff: *CAPS*: Nancy Padian, Thomas Coates, Ariane van der Straten, Judy Quan; *Zimbabwe*: Tsungai Chipato, Gertrude Khumalo-Sakutukwa, Megan Dunbar, Hazel Chinake

Project Description/Significance: Many urban and rural adolescent girls living in Zimbabwe engage in, or are at risk for engaging in, sex for economic necessities (compensated sex) to cover living expenses, including material goods, school fees and uniforms. Out-of-school girls, while not facing school-related expenses, may have a heightened need for assistance for day-to-day existence, and through their daily activities, may have increased opportunities for engaging in compensated sex than their in-school counterparts. The proposed study will focus on out-of-school girls, who are the most difficult population to access, and lay the groundwork for developing a future economic intervention targeting adolescent girls in Zimbabwe. Funds for the formative work with in-school girls are being sought elsewhere. The intervention will combine incentives to stay in school with job training, a small loan/grant program and an educational program to address compensated sex.

The specific aims of this study are:

- To gather in-depth information on the socioeconomic and behavioral determinants of participating in compensated sexual relationships
- To identify recruitment and tracking strategies necessary to create and retain a cohort
- To identify the most appropriate way to obtain consent among minors and their parents for the proposed study and the future intervention
- To characterize the target group in terms of risk behavior, reproductive health status (including HIV/STD and pregnancy) and school/employment history.

By focusing on an understudied population with heightened vulnerability to HIV/STDs and unwanted pregnancies, this study fits well with our parent grant's mission (*CAPS*, #2-P50-MN42459) of innovative national and international HIV prevention research.

## International



### HIV Transmission and Universal Antiretroviral Use in Brazil (pilot study)

Project Staff: Principal Investigator: Dr. Kimberly Page-Shafer; Co-Investigators: Drs. Mauro Schechter (Federal University of Rio de Janeiro), Eric Delwart (Blood Centers of the Pacific), Katia Alves (Fogarty Fellow, U.C. Berkeley); Project Staff: Megan McGuire.

Project Description: It is hypothesized that reduced viral load, as a result of widespread antiretroviral treatment (ART), will result in decreased transmission and incidence of HIV. However, evidence for this is indirect and has never been directly measured. Brazil currently has a program guaranteeing universal access to antiretroviral agents for persons with AIDS or advanced disease which makes it an optimal country for this investigation. As a result, we are currently piloting in two locations: Rio de Janeiro and Santos, Brazil.

The primary specific aims of the study are:

- To determine the incidence and risk factors for incident HIV infection in men and women who seek HIV testing at anonymous HIV testing sites in an area of universal HIV antiretroviral treatment (ART) access.
- To determine whether ART combination treatment is associated with increased or decreased odds of HIV transmission (as a result of decreased viral load).
- To investigate specific behavioral, biological, viral, and clinical co-factors that increase or decrease the risk of HIV transmission from those on ART to at-risk partners.

Significance: The unique public health policy of universal access to ART in Brazil makes this location an especially important place to study HIV transmission. UNAIDS estimated that at the end of 1999 1.3 million people were living with HIV/AIDS in Latin America, the majority of whom are in Brazil. In the past six years, the AIDS epidemic in Brazil has grown 7 percent in men, but almost 70 percent in women, according to the National AIDS Program in Brazil. A steady change in risk categories has been observed in the Brazilian HIV epidemic, with a declining proportion of HIV/AIDS cases attributed to homosexual activity and substantial increases in heterosexual risk groups, especially women. This study will provide much needed information about the impact of ART on HIV transmission. Secondly, this study will add greatly to our understanding of the heterosexual transmission of HIV in developing countries and allow us to identify and design appropriate strategies to control the epidemic in these settings.



## HIV Prevention Trials Network (HPTN)

Project Staff: *CAPS*: Nancy Padian, Susan Buchbinder, Thomas Coates, Grant Colfax, David Katzenstein, Yvonne Maldonado, Eric Vittinghoff, Gene Washington, Art Reingold, Ariane van der Straten, Jeanne Moncada, Sarah Glass, Judy Quan, Melanie LaPorte Smith, Alexandra Minnis, Loreen Hanak; *Zimbabwe*: Tsungai Chipato, Dr. Chirenje, Dr. Madzima, Dr. Mbivzo, Gertrude Khumalo-Sakutukwa, Joelle Brown, Tinofa Mutevedzi, Magdalene Mwale, Vicki Bunnnett

Project Description/Significance: This proposal represents a collaboration between the University of Zimbabwe - UCSF Women's Health Programme in Harare, Zimbabwe (led by Dr. Nancy Padian at UCSF), the Zimbabwe AIDS Prevention Program (ZAPP, led by Dr. Yvonne Maldonado), and the HIV/AIDS Research Group at the San Francisco Department of Public Health (led by Dr. Susan Buchbinder). Dr. Tsungai Chipato from the University of Zimbabwe is the Principal Investigator for the overall program.

Even more than the fruitful collaboration between separate HPTN sites, this combined site fosters synergy and communication between investigators representing a wide range of expertise. It is cost effective because it funds investigators and staff at the combined site to work on multiple projects. The science arising from these combined sites also benefits from the broad focus brought to prevention research by the need to integrate domestic and international concerns, and to develop prevention strategies for different modes of sexual transmission. Integration of the two community advisory boards allows us to deepen our understanding, disseminate complementary skills, and ultimately enhance the contribution of affected communities to the research agenda.

HPTN is the continuation of three existing HIVNET studies:

- HIVNET 016, an international Phase III clinical trial of the microbicidal effects of N-9 gel on STDs and HIV. A new protocol is being drafted, HPTN 035, due to the 7/2000 UNAIDS N-9 study preliminary results and HPTN 016A is now the Condom Promotion and Counseling Phase only. (Project Period of HIVNET 016: 10/01/98 – 07/01/00).
- HIVNET 015, a domestic Phase III behavioral trial comparing an intensive individualized behavioral intervention with standard counseling and testing among high-risk MSM;
- HIVNET 023, an international safety and dosing study of nevirapine for post-natal prevention of HIV transmission. In addition, we hope to be an expansion site for future Phase I trials for antiretroviral therapy (ART) and rectal and vaginal microbicides, as well as for Phase III perinatal transmission studies.

The four specific aims of HPTN follow:

1. To provide scientific expertise and leadership to the network specifically in the areas of:
  - a) rectal and vaginal microbicide and barrier contraceptive research;
  - b) identification and implementation of interventions to reduce high-risk sexual behavior;
  - c) use of anti-retroviral therapy to prevent transmission;
  - d) research on prevention of perinatal transmission;
2. To conduct and participate in Phase I, II and/or III prevention intervention clinical trials domestically and internationally;
3. To convene and maintain community advisory boards in San Francisco and in Zimbabwe and to link them;
4. To demonstrate our ability to expand to multiple prevention efficacy trials in new populations.

## International



# HIV Risk Reduction through HSV-2 Prevention

Project Staff: *CAPS*: Nancy Padian, Steve Shiboski; *Zimbabwe*: Tsungai Chipato, Marshall Munjoma, Gertrude Khumalo-Sakutukwa, Joelle Brown

Project Description/Significance: Viral sexually transmitted infections (STIs) are a significant health burden. In particular, women have limited options to protect themselves against STIs. Herpes simplex virus type 2 (HSV-2) and human immunodeficiency virus (HIV) are two of the most prevalent viral STIs. Neither of these infections is curable or preventable with available vaccines. Both have serious sequelae and implications for reproductive health. While HIV and HSV-2 infection have been demonstrated to be highly associated with each other, it has been postulated that infection with each virus may be a risk factor for infection with the other. Although both behavior change and the consistent use of condoms appear to protect against HIV, no prevention strategies for HSV-2 have been demonstrated to be effective. While this lack of effective prevention strategies may in part reflect the inadequacy of studies to date, the biology of HSV-2 — the fact that viral shedding occurs over a wide anatomic area in the genital region — suggests that condoms may be less effective for preventing transmission of HSV-2 than for preventing STIs associated with transmission through urethral and cervical secretions. Nonoxynol-9 appears effective in preventing HSV-2 infection in animal models. However, little is known about the effect of nonoxynol-9 in preventing HSV-2 infection in humans.

This AIDS-FIRCA proposal is primarily aimed at determining if HSV-2 infection is an independent risk factor for HIV acquisition, and at defining the effect of intravaginal use of nonoxynol-9 in preventing HSV-2 acquisition. This proposal outlines a 3 year prospective cohort study of 1200 HIV uninfected women attending the Spilhaus family planning clinic in Harare, Zimbabwe. Baseline clinical, microbiologic, and laboratory data, including HIV and HSV-2 serologic tests will be obtained. If we establish that infection with HSV-2 increases susceptibility to HIV, and that nonoxynol-9 prevents transmission of HSV-2, we will have revealed a modifiable risk factor for HIV, as well as an inexpensive means of preventing HSV-2 infection and its attendant sequelae. By simply adding an additional tube of blood and a diagnostic test to an established phase III trial in Zimbabwe, the study being proposed here may answer these important questions.

The primary objective of this project is:

- To assess the effectiveness of 100 mg N-9 gel in preventing male-to-female transmission of HIV through heterosexual vaginal intercourse.

The secondary objectives of this project are:

- To assess the effectiveness of 100 mg N-9 gel in preventing male-to-female transmission of chlamydial infection, gonorrhea, trichomoniasis and syphilis among women at risk of HIV infection through heterosexual vaginal intercourse;
- To determine long-term safety of 100 mg N-9 gel;
- To assess the long-term acceptability of 100 mg N-9 gel among study participants.

The specific aims of this project are:

1. To determine if HSV-2 infection is an independent risk factor for HIV acquisition;
2. To assess the effectiveness of 100 mg N-9 gel in preventing male-to-female transmission of HSV-2 through heterosexual vaginal intercourse;
3. If HSV-2 is an independent risk factor for HIV acquisition, and 100 mg N-9 gel prevents HSV-2 acquisition: To estimate the potential effect of HSV-2 prevention on HIV acquisition.



## Hormonal Contraception and the Risk of HIV Acquisition

Project Staff: *CAPS*: Nancy Padian, Ariane van der Straten, Jeanne Moncada, Judy Quan, Sarah Glass, Alexandra Minnis, Melanie LaPorte Smith, Loreen Hanak; *Zimbabwe*: Tsungai Chipato, Gertrude Khumalo-Sakutukwa, Megan Dunbar, Vicki Bunnnett

Project Description/Significance: This is a multi-center, prospective cohort study. Hormonal contraception is widely used in the developing world, including Sub-Saharan Africa where HIV incidence among “low risk” women (women not engaging in sex work) is highest. Because HIV incidence primarily affects women of reproductive age, understanding the impact of hormonal contraception on HIV transmission is a critical unanswered public health question.

The primary objective of the study is:

- To measure the effect of combined oral contraceptive (COC) and Depot-Medroxyprogesterone Acetate (DMPA) use on the acquisition of HIV infection by comparing the rate of infection among women using COCs and DMPA with the rate among women not using hormonal contraception.

The secondary objectives of the study are:

- To determine if the rate of HIV infection in HC users compared with non-users is modified by the presence of other sexually transmitted diseases (STDs).
- To measure whether the type of hormonal contraception (COC versus DMPA) has a differential impact on the rate of HIV acquisition among women.

The tertiary objective is:

- To acquire, preserve, store and ship serum, plasma and peripheral blood mononuclear cells (PBMC) for subsequent viral isolation and genetic/antigenic characterization in support of HIVNET’s HIV-1 vaccine development initiatives.

6,360 HIV seronegative women attending family planning and maternal and child health clinics in Uganda, Thailand, and Zimbabwe will be enrolled into the study over a 15-month period. A total of 2,400 participants will be enrolled in Zimbabwe.

Ancillary Studies to the main Hormonal Study

1. The Reliability of ACASI Data Collection in Harare, Zimbabwe:  
This study explores the use of automated computer-assisted interviewing technology (ACASI) on the collection of sensitive sexual behavior information in a developing country.
2. A Study of Contraceptive and Intravaginal Practices, Bacterial Vaginosis, Chronic Inflammation and HIV:  
Investigate the role of hormonal contraception in the etiology of other reproductive tract infections (RTIs). This will be conducted among the HIV-negative cohort enrolled in the parent study.
3. A Study of Contraceptive Practices, Herpes Simplex Virus and HIV:  
Investigate the role of hormonal contraception in the etiology of other reproductive tract infections (RTIs). This will be conducted among the HIV-negative cohort enrolled in the parent study.
4. Effect of Hormonal Contraception on HIV Genital Shedding among Women with Primary HIV Infection:  
The HIV Genital Shedding Study examines the role of hormonal contraception and HIV subtype on HIV genital shedding among women with early/acute, and later, chronic HIV infection.



## Access to Publicly Supported Pharmaceuticals by Racial/Ethnic Minorities

Project Staff: James G. Kahn, Principal Investigator, Stephen F. Morin, Co-Principal Investigator, T. Anne Richards, Co-Investigator, Herminia Palacio, Co-Investigator

**Project Description:** This project, funded by the Health Resources and Services Administration (HRSA), was designed to assess the facilitators and barriers in accessing HIV pharmaceuticals by racial and ethnic minorities. The goal of this study was to better understand the social and policy barriers that exist in order to identify the solutions in overcoming the racial/ethnic disparities in HIV care. The specific aims of this study were 1) to assess differential access and utilization of HIV pharmaceuticals in publicly supported programs by race and ethnicity, 2) to assess structural barriers to and facilitators of access and utilization of HIV pharmaceuticals by individuals in publicly supported programs, and 3) to assess community perceptions of access to and utilization of HIV pharmaceuticals in publicly supported programs by racial and ethnic groups.

This project looked at the racial/ethnic disparities in access to HIV medication in four states - New York, California, Florida, and Texas. These states were selected because they have the largest AIDS case populations, and because they each have distinctly different social and policy environment. This study used several data sources: 1) a review of literature on the effect of race/ethnicity on the use of HIV medication, 2) secondary descriptive and claims data for Medicaid and AIDS Drugs Assistance Program (ADAP) provided by each of the states, 3) key informant interviews with state health program administrators and senior policy makers, and 4) key informant interviews with local clinic-based benefit eligibility workers, care providers and HIV patients.

In 1999, African Americans and Latinos represented 60% of the population living with AIDS, though they represent only 25% of the U.S. population (12% and 13% respectively). A large number of African Americans and Latinos with HIV/AIDS in the US are without private insurance and rely on publicly funded programs such as Medicaid and ADAP. This project sought to look at how differences in access to HIV care by ethnic/racial minorities in publicly funded programs could be examined and linked to how each state operated its own Medicaid and ADAP program.

A review of the literature indicated that racial/ethnic disparities in utilization of HIV medication existed. Several structural barriers to HIV drug access by racial/ethnic minorities were determined. These included the legal immigration requirements in all four states, the disability requirements in California, Texas, and Florida, as well as the limit on drug benefits and rural access problems in Texas and Florida. Social barriers to utilization of HIV drugs by racial/ethnic minorities across the four states included lack of information, distrust of government, migration and immigration issues, conflicting cultural beliefs, HIV-related stigma, unstable living conditions, and substance abuse and mental health problems. The results of this project are being presented in four papers in [Public Health Reports](#).

## Cochrane Collaborative Review Group on HIV Infection and AIDS

Project Staff: Gail Kennedy, MPH and George Rutherford, MD

**Project Description:** The Cochrane Review Group on HIV Infection and AIDS has its editorial base at the University of California's AIDS Research Institute (ARI) in San Francisco. The mission of the Group is to conduct systematic reviews of randomized and other rigorously controlled studies with clinical, serologic, behavioral, economic and other outcomes relating to the prevention and treatment of HIV infection and AIDS, as well as to the organization and financing of health care services. We seek volunteers to join the Group who are interested in peer reviewing completed documents and working on the production of systematic reviews. In addition, the editorial staff has compiled a specialized database of completed trials of HIV prevention that is made available to members of the Group conducting reviews.

**Significance:** Physicians, researchers, public health practitioners, and patients are deluged with unmanageable amounts of information about the best approaches to prevention, treatment and health care delivery. To address the health information overload, systematic reviews have been developed to synthesize the vast number of studies and data sets culled from those studies. These reviews are useful to health care providers because they link and correlate huge amounts of information in order to identify beneficial or harmful interventions. For individuals, systematic reviews can help them to make more informed decisions about their health care. Policymakers can use systematic reviews to formulate practice guidelines, identify appropriate interventions for funding, and promote health care legislation grounded in sound public health science. Researchers can use the results of systematic reviews to identify opportunities for further study and to insure that they are not inadvertently investigating an intervention that has already been proven effective or ineffective. Although they can be time-consuming and slow, systematic reviews are intrinsically quicker and more cost-effective than using research funds for new studies to address questions that may already have been answered.

**Interesting Findings:** With over 100 active members from 15 countries, we presently have 9 completed systematic reviews and 43 reviews are in progress. We are focusing on producing reviews of high-priority for the developing world and resource-poor settings and have teamed with collaborators in southern Africa to produce reviews of interest to that region. Topics include male circumcision for HIV prevention, female microbicides for HIV prevention, condom promotion strategies for HIV prevention, the efficacy of combivir and trizivir treatments, and the use of broad-based antibiotics for prevention and treatment of OIs. We also are focusing on systematic reviews of interest to the developed world including HIV prevention interventions targeting ethnic and racial minorities, the efficacy of three- or four-drug treatment combinations versus two-drug combinations, issues around adherence to highly active antiretroviral therapy (HAART) and the discontinuation of prophylaxis for opportunistic infections (OIs) in people taking HAART.

We have found that reviewers need assistance in the production of reviews so we have instituted a mentoring system with more experienced reviewers offering guidance and assistance to first time reviewers. We offer training workshops in the San Francisco area for those interested in joining the Group. In addition, we have also began working closely with the South African Cochrane Center to support Group members throughout Africa.

## Enhancing Community Participation in the HIV Prevention Trial Network

Project Staff: Stephen F. Morin, Principal Investigator, T. Anne Richards, Co-Investigator, Andre Maiorana, Project Director

Project Description: The HIV Prevention Trial Network (HPTN) is a worldwide collaborative clinical trials network established by the National Institutes of Health (NIH) to evaluate the safety and efficacy of non-vaccine prevention interventions, using HIV incidence as an endpoint. This study is designed to assist the HPTN Community Working Group (CWG) in fostering partnerships between researchers and local study communities. The specific aims of the study are 1) to assess the experience of the community advisory board (CAB) members and community participation activities and 2) to assess community perceptions and preparedness among potential participants in prevention intervention trials. The goal of this project is to determine the factors that maximize community input into HPTN studies in order to inform and guide the overall activities of the CWG, as well as to help the HPTN analyze, anticipate and prepare for the ethical, community and policy issues involved in research with different populations in diverse social, cultural and geographic settings.

This project will evaluate community involvement in the HPTN domestic sites of Los Angeles, Birmingham, and Philadelphia, and the international sites in Lima, Peru; Harare, Zimbabwe; and Chiang Mai, Thailand. This study involves three procedures: 1) qualitative interviews, 2) ethnographic observations, and 3) secondary data analysis. Qualitative interviews with six research team members and six community advisory board members per site will seek to identify the resolution of ethical issues in research and lessons learned that could benefit the functioning of community advisory boards. Qualitative interviews with six potential participants in HIV prevention trials per site will attempt to determine how local participants weigh the different advantages and disadvantages of participation in prevention studies. Ethnographic observations will be conducted in all six sites to better understand the interaction between research participants and local site staff. The secondary data to be reviewed at each site will include the epidemiology of HIV, research protocols, and available information on local cultures.

HIV prevention research raises particularly complex ethical dilemmas because data are sensitive, stigma and discrimination may occur if confidentiality is breached, and there is a public health imperative to notify persons who are infected or unknowingly at high risk. Innovative HIV prevention research also raises the new ethical dilemmas of how to provide appropriate care to control groups and how to conduct research in developing countries. The HPTN must be proactive in anticipating potential ethical and policy dilemmas and resolving them through a rational and systematic process. This study sets the foundation and provides the initial mechanism whereby important policy, community, and ethical issues are to be raised and establishes the basis for constructive resolution.

Our interviewers have just come back from collecting data in Zimbabwe and we are starting to analyze the data from that site. Data analysis will continue as we visit each of the other five sites in the next two months.

## Expanding Access to HIV Care in California

Project Staff: Stephen F. Morin, Principal Investigator, Fred Dillon, Co-Investigator, Myrna Cozen, Project Director

**Project Description:** This project, funded by the Universitywide AIDS Research Program (UARP), was designed to study six California-specific policy options for expanding access HIV care. The goal of this project is to improve the uniformity and quality of the data used by advocates and policymakers for policy development and for evaluating legislative options. The specific aims of this project are 1) to systematically characterize each of six policy options for expanding HIV care in California, including populations targeted, eligibility, benefits, cost per unit of service, and legislative or regulatory changes required to implement, 2) to develop cost/benefit models to assess policy options, including formal descriptions of modeling methods, and their impact on California's state budget, and 3) to systematically evaluate the relative feasibility and acceptability of each option through key informant interviews with state legislative staff, public health officials, HIV medical care providers, treatment advocates, and people living with HIV.

In this project the research will involve quantitative projections using cost/benefit modeling, as well as qualitative descriptions of implications of each policy option from key informants. Following the analysis of both the quantitative and qualitative data, the next step is to characterize the relative feasibility and potential acceptability to decision-makers and people living with HIV of each policy option. The six policy options are as follows: 1) expanding Medi-Cal eligibility for individuals in the early stages of disease through a Medicaid waiver, 2) expanding Medi-Cal eligibility for individuals in the early stages of HIV disease through the use of California-only funds, 3) developing a return-to-work Medi-Cal buy-in for individuals with HIV who return to work from disability, 4) obtaining a WIIA demonstration project funds to provide Medi-Cal coverage to individuals with potentially disabling medical conditions prior to the onset of disability, 5) expanding the purchase of private health insurance through the Ryan White funded health insurance premium program (CARE/HIPP), and 6) creating an ADAP-Plus program to provide ambulatory care for uninsured individuals with HIV disease.

This research project has the potential to help develop better methods for objective assessment of significant health policy options. As the number of people living with HIV continues to grow in California as elsewhere in the country, the need to expand access to quality HIV care emerges as one of the highest priorities for AIDS policy. While there have been discussions of some of the six incremental expansion of access options being investigated for this project, there has not been a systematic study of the relative advantages and disadvantages using a research design to assess the potential to expand coverage and the feasibility of each option.

We recently presented at the UARP conference preliminary data. We are in the process of developing cost projections and analyzing the key informant interviews. We will be preparing a paper outlining results and implications for evidence-based policy developments.

## Exploring the Roles and Experiences of Nonscientists and Noninstitutional Members of Institutional Review Boards (IRBs)

Project Staff: Bernard Lo, MD, Principal Investigator; Sohini Sengupta, PhD, MPH, Co-Investigator

Project Description: The research design of the proposed study is cross-sectional using qualitative methods. We telephone interviewed 31 nonscientists and noninstitutional IRB members from across the country. The aims of the study are the following:

1. To explore nonscientists and noninstitutional members' perceptions of how they are treated by the other members of the IRB, the contributions they have made to the IRB process, and any barriers they have faced while serving on the IRB.
2. To explore any ethical concerns of nonscientists and noninstitutional members that the other IRB members tend to overlook.
3. To identify nonscientists and noninstitutional members' education and training needs, and recommendations for IRB reform.

Interviews will be audiotaped and transcribed. Transcripts will be read to identify and code themes. Predicted themes (e.g., roles of, contributions made by noninstitutional and nonscientist IRB members) and emergent themes will be reported to OHRP and in scholarly publications.

Significance: Institutional Review Board (IRB) members who are (a) nonscientists and (b) not affiliated with the institution, i.e., noninstitutional members, can make special contributions to the protection of human subjects because of their awareness of community values regarding research. Currently, we don't know the roles and experiences of nonscientists and noninstitutional members, and what special types of contributions, if any, they are making to their respective IRBs. This is surprising given that some of the major concerns about IRBs and the need for IRB reform at the local level have to do with enhancing education for noninstitutional and nonscientific IRB members, and making the informed consent processes for research more understandable to the study populations affected by the research. Therefore, we propose to examine noninstitutional and nonscientific IRB members' roles, what barriers they face in their roles, and how they believe their roles might be strengthened.

## High Volume Needle Exchange to Avert New Infections

Project Staff: David R. Gibson, James G. Kahn, Daniel Perales, Joseph Gurdish

**Project Description:** This project followed a cohort of injecting drug users (IDU) over a period of 21 months, comparing the HIV risk behavior of users versus nonusers of a model syringe exchange in Santa Clara County, CA. In addition, the study is modeling the effectiveness and cost-effectiveness of the exchange in averting new HIV infections.

**Significance:** Along with street outreach and drug treatment, needle exchange is a major prevention modality for IDU. The project sought to determine the magnitude of protective effect associated with use of it, in addition to its effectiveness and cost-effectiveness.

**Interesting Findings:** Comparing users with nonusers of syringe exchange, we found that use of syringe exchange has a two- to seven-fold protective effect against high-risk injection behavior. The upper bound of a seven-fold protective effect was for IDU who did not have other sources of syringes. We also found that syringe exchange pays for itself 27 times over in terms of the cost of operating needle exchange versus the cost of treating new infections that would have occurred in the absence of needle exchange.

## Policy



# The Medi-Cal Managed Care Quality and Assurance Project

Project Staff: Stephen F. Morin, Principal Investigator, Myrna Cozen, Project Director

**Project Description:** This project, funded through a subcontract with the Health Access Foundation, is designed to assess the opinions and experiences of primary care providers regarding Medi-Cal managed care plans. The specific aims of this project are 1) to obtain input from primary care providers in three northern California counties regarding their experiences with Medi-Cal managed care plans, 2) to combine the results of this assessment with secondary data on the plans to produce a set of criteria by which to evaluate the quality of a Medi-Cal managed care plan, 3) to demonstrate that plans can be evaluated using those criteria and presently available information, and 4) to present the criteria in a format that can be incorporated into consumer-oriented report cards evaluating quality and performance of Medi-Cal managed care plans. The main goal of this study is to produce reliable sources of information that can be used by health care organizations and consumer advocacy groups to evaluate the performance of Medi-Cal managed care plans.

This project will assess opinions and experiences of Medi-Cal managed care primary providers in the counties of San Francisco, Alameda, and Santa Clara through the use of a mail survey and secondary data sources. A mail survey querying the primary care provider's practice setting, their own and their patients' demographic characteristics, revenue sources, and experiences with Medi-Cal and Medi-Cal managed care will be sent to General Practitioners, Family Practitioners, Internists, Pediatricians, OB/GYNs and Family Nurse Practitioners. Previously published reports on Medi-Cal managed care with data on the number of people enrolled in the plans, administrative structure, adequacy of referral panels, and reports of consumer complaints will be used in combination with the results of the mail survey to produce a set of quality criteria.

Managed care is a complicated system of health care delivery that requires a high level of consumer skills to navigate, ready access to a telephone, and a high level literacy. Medi-Cal beneficiaries, by virtue of being low income and often from minority communities, often encounter a range of problems that impede access to appropriate care. Currently physicians play no role in quality assessment of Medi-Cal managed care programs. Furthermore, Medi-Cal consumers have no independent source of information to use in choosing a plan or in advocating for improved quality of care. This project will result in an independently produced source of information on quality of care in Medi-Cal managed care programs which can be used by consumers to choose a plan and by advocates and policymakers in their efforts to improve and enforce quality of care standards.

We are currently in the pilot phase of this study distributing surveys to the Pilot Representatives of the UCSF/Stanford Collaborative Research Network (CRN). After the survey has been revised and finalized based on the results of the pilot, it will be distributed to physicians in the three counties.

## Perception of HIV Counseling and Testing by Racial/Ethnic Minorities

Project Staff: Steve Morin, Principal Investigator, T. Anne Richards, Co-Investigator

Project Description: For this project, funded by the Lloyd Foundation, differential utilization of HIV counseling and testing services among racial/ethnic minorities was assessed. This study was designed to compliment a larger study examining differential access to and utilization of HIV pharmaceuticals by race/ethnicity. The specific aims of this study were 1) to assess health care providers perception of barriers and facilitators of access to and utilization of publicly supported HIV counseling and testing programs by racial and ethnic minority patients, and 2) to assess consumer perceptions of HIV counseling and testing programs by racial and ethnic minorities. The goal of this project was to determine community perception toward HIV testing in order to produce better recommendations on how to successfully promote knowing one's HIV status in racial/ethnic communities.

Initially thirty-two qualitative interviews were conducted at four clinic sites that predominately served African Americans, Latinos, Asian and Pacific Islanders, and Native Americans respectively in San Francisco and Oakland. Health care providers were asked about their perceptions of the clinic population's use of counseling and testing, motivation for testing and returning for test results, and follow through on referral for primary care. Patients were asked to describe their experiences, reactions and motivation behind testing, counseling and care. In addition to the qualitative interviews, ethnographic observations were reported and secondary data for the clinics was obtained.

There is much public concern over the apparent disparities in the incidence and health outcome of racial and ethnic minorities with HIV/AIDS. Two factors potentially responsible for this are failure to detect HIV infection until late in the course of the disease and lower utilization of HIV medication and care by racial/ethnic minorities. This study helped to better understand the perceptions of health care providers and racial/ethnic patients on these concerns.

Several reasons emerged in each of the different clinics for failure to test for HIV or the high frequency of testing late in the disease progression. These included limited knowledge or lack of information across all four clinics, the personal conflicts of unemployment and homelessness in the Latino, African American, and Native American clinics, as well as a distrust of institutional testing in the African American and Native American clinic. The findings of this study are being reported in combination with the findings of another study on access to HIV pharmaceuticals by racial/ethnic minorities in a paper in [Public Health Reports](#).

## The Policy of AIDS Vaccines: Exploring Legislative Options for Advancing AIDS Vaccines Research and Delivery

Project Staff: Stephen F. Morin, Principal Investigator, Chris Collins, Co-Investigator

**Project Description:** The project, funded by Until There's A Cure Foundation, was designed to review the various legislative options for expanding research and development of AIDS vaccines and securing their delivery around the world. The goal of this project was to determine the policy barriers and facilitators that exist in the development and deployment of an effective vaccine in order to create more effective guidelines and suggestions for policy in this area. The specific aims of this study were 1) to assess the "push" mechanisms designed to spur research and development on AIDS vaccines (including tax incentives, partnerships, and manufacturing capacity) and 2) to assess the "pull" mechanisms designed to assure that AIDS vaccines will be purchased for use in developing countries (including purchase funds and tiered pricing).

The basic assumption of this study is that policy makers have critical roles to play in determining the ultimate public health effectiveness of a vaccine. Policy makers need to tackle economic disincentives for investment in research, the lack of a paying market for vaccines in poor countries, inadequate health care infrastructures, regulatory reforms, and protection of clinical trial participants. There are several ways in which policy action is fundamental in this area.

This project is important because a vaccine for HIV would be an extremely powerful prevention tool in the fight against AIDS, particularly in the developing world. However, real disincentives exist for private sector investment in vaccine products destined for developing countries. Poorer countries often have to wait a decade or more to receive a vaccine after it has been licensed in the United States. Policy makers can make a significant contribution to accelerating vaccine development and delivery.

We have determined that a combination of "push" and "pull" policy changes are needed to affect the many links in the vaccine development and delivery chain. Ensuring the ability to purchase and deliver AIDS vaccines should be a top policy priority in the coming years. Other policy actions, including tax incentives for research and delivery, should be pursued but not be viewed as substitutes for creating a credible market for vaccines. No one knows which mechanisms will be most effective, but it is clear the existing system of vaccine development and delivery is neither as efficient nor as equitable as it could be.

We are currently finishing the final revisions for a policy monograph on the findings of this study. The monograph will be distributed to all members of the US Senate and House of Representatives, various AIDS organizations, and other interested groups as well as being available on HIVInsite (<http://hivinsite.ucsf.edu/>).

## Systematic Reviews of HIV Behavioral Prevention Research in U.S. Minority Populations

Project Staff: Lynae Darbes, PhD, Gail Kennedy, MPH and George Rutherford, MD

**Project Description:** The Surgeon General's Leadership Campaign on AIDS is supporting the production of systematic reviews of all controlled studies of interventions designed to prevent HIV infection in communities of color in the US. The reviews focus on four risk groups (men who have sex with men/gay men, heterosexuals, youth/adolescents, and injection drug users) within each of the following communities of color: African-American, Latino/Hispanic, Asian-American and Pacific Islander, and American Indian and Alaskan Native. The reviews are being conducted by the Cochrane Collaboration's HIV/AIDS Group (based at UCSF), in collaboration with the Centers for Disease Control and Prevention. The reviews entail the following steps: a comprehensive systematic search for available intervention studies; contacting current researchers regarding ongoing relevant research; describing characteristics of identified studies in terms of the targeted population, components of the intervention, demographics of the participants, research design and study outcomes; summarizing the findings of both successful and unsuccessful interventions; and identifying research gaps.

**Significance:** Recent statistics have indicated a substantial increase in the number of HIV infections in communities of color across all risk groups. For example, a study conducted by the CDC in six U.S. cities found that nearly one in every three African-American MSM has HIV. Prevention efforts to stem the increase of HIV have been undertaken throughout the epidemic. However, few reviews in the extant literature have focused specifically on high risk groups within communities of color. Thus, our knowledge of successful prevention efforts across both communities of color and risk groups is limited. As a result, the Surgeon General's Leadership Campaign on AIDS is partnering with the Cochrane Collaboration's HIV/AIDS Group to identify effective prevention interventions for communities of color in an effort to help prevent the further spread of HIV/AIDS.

**Interesting Findings:** Preliminary results indicate that few HIV prevention efforts have specifically targeted communities of color. In particular, compared to other risk groups, prevention interventions specifically focusing on men of color who have sex with men are severely lacking. This is especially striking given the number and scope of studies that have been conducted since the beginning of the epidemic. An effort needs to be made to include people of color in HIV prevention evaluation research. Researchers who conduct prevention interventions with people of color should include analyses of the findings by race/ethnicity, when feasible.

## The Use and Cost-Effectiveness of New HIV Tests

Project Staff: Kathryn A. Phillips (PI), Diane Binson, James Dilley, Ron Bayer, Wolfgang Sadee, David Veenstra, James Chen, Heidi Skolnik

Project Description: This project consists of several interrelated projects:

- Surveys of individuals' preferences for different types of HIV tests
- A review of new HIV counseling and testing guidelines issued by the CDC for the general population and pregnant women
- Analyses of the economic and societal implications of the use of genotyping to individualize HIV drug therapies

Significance: There has been a long and acrimonious debate over the purpose and methods of HIV counseling and testing – a debate that reflects the history of the entire AIDS epidemic. Two important trends are now changing counseling and testing approaches and policies: (1) the development of new testing methods and uses for testing (2) an increased emphasis on more routine testing. In these series of studies, we are analyzing the historical, current, and future implications of these trends.

Interesting Findings:

- Persons being tested at a public clinic generally preferred that type of test, even when other types of tests were posed as additional no-cost options. There was also substantial interest in home self-tests, but there was little interest in home collection tests. Respondents particularly valued the attributes of accuracy/timeliness and privacy/confidentiality. We conclude that individuals' needs are not fully being met by current testing options, particularly the lack of home self-tests and rapid tests that are highly accurate.
- The new CDC guidelines are a carefully crafted attempt to simultaneously increase the numbers of HIV infected persons who know their HIV status, while maintaining the historical emphasis on prevention counseling to effect behavior change. However, there are several disturbing questions about how the guidelines will be interpreted and implemented.
- The use of genetic information to target HIV drug therapies holds great promise for reducing drug resistance in a cost-effective manner. However, there has been little social science research to examine the societal and economic implications.

## Women's Perceptions on Universal, Routine HIV Testing

Project Staff: Bernard Lo, MD, Principal Investigator; Sohini Sengupta, PhD, MPH, Co-Investigator

**Project Description:** The Institute of Medicine recently recommended universal HIV testing as a routine component of prenatal care for all U.S. pregnant women. To date, no research has been done to examine how to enhance acceptance of universal, routine HIV testing for pregnant women who are considered to be the highest at risk for HIV infection and perinatal transmission: Black and Hispanic women. That is, if understanding and acceptance from pregnant women of color with this process are not commensurate with those of policymakers, they may forego utilizing prenatal care in a timely fashion. This study will explore U.S. pregnant women's perceptions of this change in testing policy using qualitative and quantitative research methods. Seventy-eight individual interviews, 45 minutes in length, will be conducted with U.S. Black, non-Hispanic and Hispanic pregnant women seeking prenatal care at community-based or hospital clinics in San Francisco, Washington, D.C., and Chapel Hill, North Carolina. The interview instrument will consist of a sociodemographic questionnaire that includes HIV risk assessment questions, and a qualitative interview guide developed for this study. Research questions will be to (a) explore participants' experiences with current prenatal HIV testing procedures, and (b) identify pregnant women's perceived risks and benefits of universal, routine prenatal HIV testing under the new recommended policy. Interviews will be audiotaped and transcribed. Transcripts will be read to identify and code themes. Predicted themes (i.e., experiences with prenatal HIV testing and perceived risks/benefits of universal, routine HIV testing) and emergent themes will be used to develop written educational materials addressing pregnant women's concerns and priorities about HIV testing and treatment under this health policy change.

**Significance:** To date, no research has been done to explore the acceptability of the new recommended policy of universal, routine HIV testing for pregnant women who are at the highest at risk for HIV infection and perinatal transmission: Black and Hispanic women. If universal, routine HIV testing is unacceptable to them, they may forego HIV testing or even timely prenatal care. In particular, because of discrimination and distrust of medical professionals, they may be more reluctant to utilize prenatal care that is offered to them, or to which they have access. If this occurs, the policy will have the opposite effect than what was intended. In order to effect this recommendation into policy successfully, a better understanding is needed of Black and Hispanic pregnant women's experiences with utilizing prenatal care. Within these contexts, a closer look is needed at their experiences with prenatal HIV testing under the current PHS guidelines, in part, to compare their experiences with what would be implemented under the new recommendations. Second, identifying their perceptions of the benefits and risks associated with universal, routine HIV testing would help ensure that the policy, as formulated and implemented, would be responsive to the needs and concerns of pregnant women who do not have any access to prenatal care.

## Primary Prevention



### Seropositive Urban Men's Intervention Trial

Project Staff: Cynthia Gomez, PhD, Colleen Hoff, PhD, Bonnie Faigeles, MPH, William Woods, PhD, Carmen Mandic, MPH, Byron Mason, Tim Matheson, PhD, Nick Alvarado, Dinah Usog, Raven Mahosadha, Angel Gil, Jennifer Pittman

**Project Description:** The Seropositive Urban Men's Intervention Trial (SUMIT) is a randomized controlled trial of an intervention designed to reduce the risk of HIV transmission by HIV-seropositive (HIV+) men who have sex with men (MSM) to sex partners who are not infected with HIV. The intervention consists of a six-session intervention and was based on formative and pilot research. The purpose of this study is to test a 6-session multi-component HIV intervention developed to reduce HIV transmission among HIV+ MSM to sex partners whose serostatus is negative or unknown.

The study design is a randomized controlled trial with longitudinal follow-up. A total of 500 HIV-seropositive MSM will be recruited over a period of under two years. We conduct baseline assessments until we have collected data on a cohort of approximately 100 men (6-8 weeks estimated time). This group of 100 men is randomized to one of two arms: a six-session enhanced intervention consisting of six semi-structured intervention sessions or a standard-of-care intervention consisting of one HIV-related information and discussion session. Risk behavior will be assessed at baseline, three months and six months after intervention.

We also collect biologic samples at baseline and six-month follow-up assessments, which are tested for evidence of sexually transmitted disease (STD) and, at baseline only, verification of HIV seropositive status. STD data will serve as a descriptive supplement to primary and secondary outcome measures and will not be used to determine the effectiveness of the intervention with regard to reducing unprotected sexual activity with HIV seronegative/unknown status partners.

**Significance:** As part of our earlier research, over 400 HIV+ MSM were recruited to provide data regarding their sexual behaviors, drug-use practices, and disclosure of HIV status. Many men reported feeling isolated, stigmatized and uneasy disclosing their serostatus to partners. Many felt that prevention programs they had participated in were too narrow in scope and did not attract ethnic diversity. The SUMIT intervention addresses many of these issues.

**Interesting Findings:** We do not have data available from this study yet. However, many men who participated told us anecdotally that they enjoyed the opportunity to talk about being HIV+ and being with so many other HIV+ men. They liked that we were able to integrate social time, fun, food and serious discussions into the program and appreciated the opportunity to address difficult issues in a safe environment. We have been very successful recruiting a diverse sample of participants, approximately half of whom are men of color.

## Primary Prevention



### Unity Project

Project Staff: Margaret Chesney, Principal Investigator; Steve Morin, Co-Investigator; Mallory Johnson, Co-Investigator/ Clinical Supervisor; Craig Waldo, Co-Investigator; Joanne Mickalian, Project Director; Tom Holt, Clinical Supervisor; Neal Carnes, Recruitment Coordinator/Assessment Interviewer; Jo Laurence, Recruiter; Larry Lariosa, Jennifer del Val, Sheri Storey, Magaly Pena, Tanya Stallworth, Assessment Interviewers; Steve Bruce, Assessment Quality Assurance; Julia Lim, Project Assistant; Bettina O'Brien, Norma Jean Van Volkinburg, Michael Schwartz, David Olem, Nina Rodrigues, Facilitators.

Project Description: The Unity Project is a five-year study being conducted at four locations: San Francisco (University of California at San Francisco: <http://caps.ucsf.edu/>; 74 New Montgomery, Suite 600), Los Angeles (<http://chipts.ucla.edu/>), Milwaukee, and New York (<http://www.hivcenternyc.org/>). The Unity Project is funded by the National Institute of Mental Health (NIMH). In San Francisco, Dr Margaret Chesney and Dr Steve Morin of the Department of Medicine serve as the Principle Investigators.

At each site, the study will enroll 300 HIV positive people, 18 years of age or older, equally divided among men who have sex with men (whether self-identified as gay or bisexual, or not), women, and injection drug users (current or former). We are conducting the Unity Project to learn about different ways to help people who are living with HIV. The purpose of the research is to test a program developed to help people living with HIV to live longer and healthier lives as well as to reduce the risk of passing HIV on to others. Enrolled participants are randomly assigned (by chance) to either engage in the 15 one-on-one meetings immediately or a modified version later in the study. The overall goal of the meetings is to give the participant a greater sense of control over many aspects of his/her life.

Significance: As a result of medical treatment advances, greater numbers of Americans are living with HIV infection and will be able to live in good health for longer periods of time. In addition, there is now considerable evidence that a substantial number of HIV+ men and women have difficulty avoiding sexual and drug use transmission risk behaviors. Following notification of their HIV+ serostatus, many HIV-infected individuals make and maintain changes in their sexual and injection drug use practices to avoid transmitting HIV to others (Cleary et al., 1991; Higgins et al., 1991). At the same time, there is growing evidence that a substantial number of persons living with HIV continue to engage in unprotected sexual and injection risk activities. This project will examine social, psychological, situational, and contextual factors that influence and mediate patterns of continued high-risk sexual and drug injection behavior among HIV+ people, including affective factors such as affective states, coping patterns, and psychological distress; self regulatory factors such as substance use; and contextual and relationship factors such as serostatus disclosure, relationship status, and economic and "survival" sex patterns.

Interesting Findings: Recruitment for the Unity Project currently involves several methodologies, including outreach to community-based organizations serving people living with HIV, substance users, sexual minorities, and women.

## Primary Prevention



### Berkeley, Alameda & Sonoma Evaluation Study (BASES)

Project Staff: Co-Principal Investigators: Olga Grinstead & Diane Binson; Monica Cezareo, Moher Downing, Beth Freedman, Sherry Fung, Cynthia Gomez, Tor Neilands, Thomas Riess, Karen Vernon and Bill Woods

Project Description: The BASES project at UCSF's Center for AIDS Prevention Studies (CAPS) is collaborating with Alameda County Health Care Services, Berkeley Public Health Department, Sonoma County Department of Health Services and eight community based organizations [Alliance Medical Center, CAL-PEP, Drug Abuse Alternatives Center, Face to Face, Pacific Center, Southwest Community Health Center, Tiburcio Vasquez Health Center and West Oakland Health Center] to conduct outcome and process evaluations of HIV prevention interventions targeting men-who-have-sex-with-men (MSM) and people of color (POC) [Latinos and African-Americans], and to provide technical assistance (TA).

The Specific Aims of the project are: 1) to conduct detailed, specific outcome evaluations of MSM and POC initiatives; 2) To conduct cross-site data analysis of outcomes; 3) to provide technical assistance and capacity building through individual consultation and skills-building workshops.

#### Outcome Evaluation

Our project team will be conducting outcome evaluations of one-on-one counseling programs for MSM interventions in the Berkeley and Sonoma health jurisdictions, and for POC interventions in the Alameda and Sonoma health jurisdictions. We will conduct baseline interviews with clients about HIV risk behaviors before they enter the programs. We will then conduct follow-up interviews approximately three months later to assess behavior change. We intend to conduct data analysis across health jurisdictions and populations. Cross site analysis will compare differences in changes in risk behaviors, pre- and post-intervention, as well as variations in implementation, utilization and satisfaction between risk groups (e.g. MSM vs. POC), geographic areas (metropolitan vs. non-metropolitan) and class differences (e.g. middle vs. working class).

#### Process Evaluation/Technical Assistance

We will provide TA to each health department and collaborating community based organizations to build their capacity for both their intervention and evaluation programs. Through the CAPS Technology and Information Exchange (TIE) Core, we can provide a wealth of TA and capacity building resources. TA will include educational materials, individual consultation and skills building workshops as needed. We will also provide consultation and training on research methods (qualitative techniques and survey design and implementation), as well as assistance on such topics as recruitment, program implementation, literature and internet searches, selecting and adopting/adapting scientifically evaluated HIV prevention interventions, and the development of scientist-community collaborations.

## Primary Prevention



### Community Mobilization of Out-of-Treatment Injecting Drug Users

Project Staff: David R. Gibson, Susan Kegeles, Neil M. Flynn, Michele Ginsberg, Thomas J. Coates

**Project Description:** This study is an evaluation of a multicomponent community-level intervention to prevent HIV among injecting drug users (IDU). The intervention is predicated on a social change orientation designed to change IDU community norms regarding safer injection and safer sex. Components include street outreach, small group empowerment sessions, an IDU-operated syringe exchange, a newsletter for untreated IDU, a late-night television show, and convenience advertising targeted to venues frequented by IDU. To evaluate the intervention, cross-sectional surveys of IDU were conducted both before and after implementation of the intervention in Sacramento and in San Diego, the comparison site, which received no intervention.

**Significance:** The project seeks to enlist IDU in mobilizing their communities against the threat of HIV, with the goal of "changing the culture" supporting high-risk behaviors.

**Interesting Findings:** Data analysis is underway to determine the impact of the intervention. If the intervention appears to have been effective in Sacramento, we will attempt to replicate the result, by implementing and evaluating it in San Diego.

## Primary Prevention



### Creating Community Between Young and Older African-American Men Who Have Sex with Men in the East Bay

Project Staff: Pilgrim Spikes and Susan Kegeles

Project Description: This project seeks to explore ways to decrease social isolation and sexual risk behaviors of young African American men who have sex with men (AAMSM) by:

1) investigating survival strategies used by younger (18-25 years of age) and older AAMSM (40 years of age and over) to help them cope with their racial and sexual identities; 2) promoting contact with older AAMSM, who can provide informational support, emotional support, and serve as role models, and 3) exploring the development of a formal mentoring program between younger and older AAMSM at a community-based organization.

Ninety-six AAMSM will be recruited in the East Bay to complete surveys and participate in focus groups.

Significance: Young African-American men who have sex with men (YAAMSM) are at high risk of becoming HIV positive and are disproportionately represented in the number of new HIV infections being reported. YAAMSM report both social and emotional isolation from family and community structures (church, Black community, and gay white community) because of their sexual and racial identities, which in turn may be associated with risky sexual behavior. Culturally responsive intervention programs are needed to halt the spread of HIV among all AAMSM, especially the young.

This study expands on one of the interventions suggested by young AAMSM to address HIV in their communities.

Results from the study will be shared with AAMSM community for feedback.

## Primary Prevention



### Draw the Line/Respect the Line: An HIV Prevention Intervention for Middle School Children

Project Staff: Barbara V. Marin, Cynthia Gomez, Steve Gregorich, Estie Hudes (CAPS) and Douglas Kirby, Karin Coyle (ETR Associates, Santa Cruz)

Project Description: Draw the Line/Respect the Line is an effective educational curriculum that assists students in developing their personal sexual limits and practicing skills needed to maintain those limits even when they are challenged. The Draw the Line curriculum utilizes small group discussions, role playing, stories, games and other approaches to actively involve participants in the learning process and help them connect the learning to their own lives. It involves 19 lessons, provided between 6<sup>th</sup> and 8<sup>th</sup> grades.

Draw the Line/Respect the Line was developed as part of a research project funded by the National Institute of Mental Health. The researchers and educators involved in this project spent several years developing and pilot testing the curriculum. Students in focus groups provided information about how youth think and feel about sex and they provided feedback about lesson ideas. To evaluate the curriculum, 19 middle schools were randomly assigned to treatment or control groups. Students whose parents had consented to their participation (N=2829) were surveyed before receiving the curriculum in 6<sup>th</sup> grade and at the end of 7<sup>th</sup>, 8<sup>th</sup> and 9<sup>th</sup> grades (90%, 87% and 63% follow-up respectively) regarding their sexual behavior, attitudes, peer norms, opportunities for sex, and intentions to have sex.

Significance: The Draw the Line/Respect the Line curriculum is one of the first developed for students in middle school. Given that a substantial proportion of middle school youth may be sexually active, delaying the onset of sexual activity is an important goal.

Interesting Findings: Analyses suggest that the curriculum delayed the onset of sex for boys, but not girls, through the 9<sup>th</sup> grade. High proportions of girls reported having a boyfriend who was 2 or more years older, and both boys and girls with older boy/girlfriends were more likely to report being sexually active.

Program will soon be available from ETR Associates (1-800-321-4407; [www.etr.org](http://www.etr.org)).

## Primary Prevention



### Evaluating HIV Prevention Interventions for High-Risk Asian and Pacific Islander Men Who Have Sex With Men

Project staff: Tooru Nemoto, Don Operario, Toho Soma (CAPS staff); Daniel Bao, Alberto Vajrabukka, Huy Le, Sheryl Uyan (Asian & Pacific Islander Wellness Center staff).

Project description: The purpose of this study is to evaluate an HIV prevention modality targeting high-risk Asian and Pacific Islander (API) men who have sex with men (MSM). The study will focus on two high-risk groups among API MSMs: 1) youth aged 18-24, and 2) HIV positive people. We have conducted focus groups with both target populations to describe current concerns around HIV and other health issues. Findings from these focus groups helped to finalize the curriculum and to formulate survey measures.

The intervention will consist of an intensive weekend retreat program, and is based upon a curriculum currently implemented at the API Wellness Center. The intervention program will be evaluated on its effectiveness by comparing outcome measures at three instances: pre-intervention, post-intervention, and 3-month follow-up. We plan on having 120 youth and 80 HIV positive people from the San Francisco Bay Area participate in the intervention.

Significance: This HIV prevention evaluation study will be the first in the nation to target API MSM youth and HIV+ people. The study findings and experience will be disseminated through networks among API-focused AIDS service organizations in California and the rest of the nation, with the aim of providing culturally competent services to this understudied population.

Interesting findings: To date, we have conducted all focus groups and a pilot study for youth. Recruitment for the intervention has been a challenge, as little intervention research in the Asian community has been conducted before. To deal with this situation, the API Wellness Center has restructured its outreach efforts.

## Primary Prevention



### The Mpowerment Project: A community level HIV prevention intervention for young gay/bisexual men

Project Staff: Susan Kegeles, Ph.D.; Robert Hays, Ph.D.; Greg Rebchook, Ph.D.; Lance Pollack, Ph.D.; Pilgrim Spikes, Ph.D.; Ben Zovod; Brady Ralston

**Project Description:** The Mpowerment Project is a community level HIV prevention intervention designed to reduce the frequency of unprotected anal intercourse among young gay/bisexual men, ages 18-29, by mobilizing young gay men to support each other about safer sex and to build a stronger, healthier young gay men's community. It is the only scientifically-developed and empirically-tested intervention that has been shown to reduce HIV sexual risk taking behaviors among young gay men. The Mpowerment Project meets the CDC's Prevention Research Synthesis project criteria for relevance and methodological rigor, and it has the positive and significant behavioral/health findings required to be listed in the *Compendium of HIV Prevention Interventions with Evidence of Effectiveness*.

**Significance:** Young gay/bisexual men are often invisible in society and have few support resources available. Young gay men are more likely than their non-gay peers to leave home at an earlier age, suffer from depression, use alcohol and drugs, and engage in behaviors that put them at risk for HIV infection. Several studies have documented alarmingly high rates of HIV infection among young gay/bisexual men. There are few positive role models for these young men, and negative images of homosexuality abound. The Mpowerment Project is a gay-positive and sex-positive peer-based intervention that relies on peers as agents of change since peers exert tremendous influence at this stage of life. The Mpowerment Project is based on an empowerment model in which young men take charge of the project because when individuals are actively involved in finding and implementing solutions to their problems, the behavior change is more lasting. The project draws on the theory of diffusion of innovations, which suggests that people are most likely to adopt new behaviors that have already been accepted by others who are similar to them and whom they respect. The project focuses on young gay men's social concerns, since formative research indicated that HIV is not particularly motivating or captivating for young gay men. Hence, the program relates HIV risk reduction to the satisfaction of other, more compelling needs. The goal of the program is to create a stronger and healthier young gay men's community in which safer sex becomes the mutually accepted norm.

**Interesting Findings:** Program evaluation data from the original study in Santa Cruz, CA, Santa Barbara, CA and Eugene, OR showed that the intervention was successful in reducing rates of unprotected sex among young gay/bisexual men who lived in the communities when the intervention took place. The proportion of men who engaged in unprotected anal sex decreased from 38.3% to 30.9% (-19.3% relative reduction), with a reduction from 19.2% to 13.6% (-29.2% relative reduction) with non-primary partners, and a reduction from 57.7% to 41.8% (-27.6% relative reduction) with boyfriends. Preliminary evaluation data from our current study in Albuquerque, NM, Austin, TX, and Phoenix, AZ show that the Mpowerment Project was able to stave off enormous increases in risky sex with casual partners that we documented in our non-intervention communities, and in some groups of young gay men, to reverse the trend. The intervention was intentionally designed to be easily adaptable to each community's culture and social environment, and although the framework of the program remains the same across communities, it has been successfully tailored by each community.

## Primary Prevention



### Mobilizing Methamphetamine Users to Prevent HIV/AIDS

Project Staff: David R. Gibson, Peter Simpson, Neil M. Flynn

Project Description: This project is a randomized trial of small-group empowerment sessions as an HIV prevention modality. Based on a diffusion of innovation approach, the sessions are designed to mobilize the methamphetamine using community in Sacramento to adopt norms supporting safer injection and safer sex. Naturally occurring friendship networks of IDU will be randomized to the experimental intervention or to a comparison group.

Significance: Social change interventions have the possibility to change norms of entire communities or populations.

Interesting Findings: The intervention is being implemented in Sacramento, CA. The evaluation will be complete by August 2002.

## Primary Prevention



### Drug Abuse Treatment for MTF Transgenders

Project Staff: CAPS Tooru Nemoto, Ph.D., JoAnne Keatley, MSW, Don Operario, Ph.D., Pedro Arista, Dee Lila Camenga, Anna Fernandez, Lally C. Adao; Walden House: Mardell Gavriel, Psy.D., Gina Eichenbaum, LCSW, Darolyn Fox

Project Description: This is a two-pronged program to provide culturally and gender-appropriate substance abuse intervention and treatment services to the MTF transgender population. One component, the Community Living Space Project (CLSP) will provide participants the opportunity to attend workshops addressing substance abuse, HIV, commercial sex work, and general life skills. The second component of our program is the Walden House Transgender Recovery Program (WH-TRP), which will expand current residential treatment programs to address the unique needs of MTF transgender clients. WH-TRP will provide expanded therapy, counseling, curricula, mentorship programs, and life training skills for this population. We will evaluate both projects to assess the impact of expanded services on program retention and success rates and on participants' drug use, sexual behavior, HIV-related attitudes, and health and well being.

The two project teams will initiate a MTF Transgender Network composed of local community-based organizations and AIDS service organizations that work with transgenders. This MTF Transgender Network will meet regularly throughout the project to ensure the cultural- and gender-sensitivity of programs, discuss emerging issues in transgender health, and strategize toward long-term solutions for drug and HIV issues confronting this population. We will disseminate findings from CLSP and WH-TRP to members of the MTF Transgender Network, to national organizations working with the transgender community, at national HIV and public health conferences, and in scientific journals.

Significance: This study provides an innovative intervention and treatment program to address substance abuse and HIV risk among male-to-female (MTF) transgenders. Our prior research has revealed alarming levels of high-risk drug use, sexual behavior, and injection hormone use. An array of psychological, socioeconomic, and cultural forces exacerbate drug and HIV vulnerability in this population, including depression, stigmatization, racism, poverty, and victimization. Moreover, our findings indicate a desperate need for culture- and gender-sensitive substance abuse treatment programs for MTF transgenders.

## Primary Prevention



### Project HIP HOP (Health in Prison, Health out of Prison)

Project Staff: Olga Grinstead, Diane Binson, Bonnie Faigeles, Bill Woods, Kathleen McCartney (CAPS staff), Barry Zack, Katie Kramer, Ricardo Bracho, Carolyn King, Merjo Roca (Centerforce staff)

Project Description: The purpose of Project HIP HOP is to design and test an intervention to reduce HIV, STD and hepatitis risk among young (18-29 years old) men who are being released from prison. In this study we are comparing two interventions. One intervention occurs prior to release and focuses on HIV, STD and hepatitis risk only. The other intervention occurs both before and after release and addresses a broader range of issues relevant to young men leaving prison (e.g. job skills and placement, housing). The intervention was developed after two years of formative research with young men leaving prison and with service providers. The intervention is based on principles of harm reduction, motivational enhancement and prevention case management. The study, funded by the Centers for Disease Control and Prevention, is also being conducted at sites in Mississippi, Rhode Island and Wisconsin. We will recruit 125 men at each site.

Significance: There is an incarceration epidemic in the United States. There are currently 2 million Americans incarcerated, and 4 million more on probation or parole. As a result of the "war on drugs," there is a concentration of injecting drug users in prison and a corresponding concentration of individual living with HIV and AIDS. Consequently, incarceration provides an opportunity to intervene with large numbers of at-risk individuals who might be difficult to reach or difficult to engage in prevention education in the non-prison community. In this study we focus on young men who are less likely to have been infected and more likely to be serving short sentences and returning to the community.

Interesting Findings: In addition to testing the effectiveness of the two interventions, we also expect to gain valuable information about the lives of young men before, during and after incarceration. This information will be essential to understanding the outcome of the intervention trial and in developing additional interventions for these young men and for their sexual and needle-sharing partners in the community. We are also collecting detailed information about retention and tracing and data on the cost of the interventions so that the cost-effectiveness of the intervention can be assessed.

## Primary Prevention



### VOICE: A Prevention Intervention for HIV Seropositive (HIV+) Injection Drug Users (IDUs)

Project Staff: Cynthia Gomez, Kelly Knight, Carol Dawson-Rose, Paula Lum, Catherine Lyons, Starley Shade, Sonja Mackenzie, Byron Mason, Barbara Garcia, Jeff Moore, Erin Rowley

**Project Description:** The VOICE Project is a randomized controlled trial of a prevention intervention for HIV+ IDUs funded by CDC and HRSA. UCSF is one site in this multi-site collaboration that includes New York Academy of Medicine, John Hopkins University, and University of Miami. The intervention seeks to decrease risky sex and drug-taking behaviors, increase healthcare utilization, and increase adherence to HIV medications among HIV+ IDUs. Based on our formative research (the VENUS Study) we designed a peer mentorship training intervention that teaches HIV+ IDUs risk reduction and health care management skills while highlighting their importance as valuable mentors to other HIV+ IDUs. Because HIV+ IDUs often have problematic relationships with services, this intervention includes an experimental agency volunteer component to increase service delivery knowledge, utilization and resource expertise. 375 HIV+ IDU men and women will be recruited from San Francisco and the East Bay.

**Significance:** While many studies have addressed the HIV prevention needs of IDU, few have specifically focused on the risk-reduction needs of HIV+ IDU. In fact, prevention needs of HIV+ individuals have been largely ignored until relatively recently. Attention to this population is critical because some HIV+ IDU continue to engage in risky sexual and drug injection practices. Moreover, substance use, mental illness, homelessness, and other factors can make it particularly difficult for HIV+ IDU to access and utilize medical care and adhere to HIV treatment regimes. Poor adherence may increase the transmissibility of HIV and contribute to the emergence of drug resistant strains of HIV. Targeted intervention strategies for HIV+IDU need to be tested and disseminated.

**Interesting Findings:** Selected initial findings from the VENUS Study:

- HIV+ IDUs qualitatively reported increased drug use, isolation, depression, and risk behavior when first diagnosed HIV+.
- HIV+ IDUs described participation in formal and informal peer education and support to other HIV+ drug users.
- Half of the participants who had a main sex partner reported that partner's status as HIV- or HIV unknown.
- Unlike HIV+ MSM, HIV+ IDUs do not seem to significantly decrease their sexual risk taking behaviors with HIV negative/unknown status partners when compared to HIV+ partners.
- Sexual risk was driven by a need to preserve intimacy in relationships, power dynamics within the drug-sex economy, and lack of skills toward HIV disclosure.
- Almost all IDUs in this sample reported access to and utilization of HIV care, but many verbalized difficult barriers to consistent utilization and medication taking.
- Women were less likely than others to be taking HAART when indicated by self-reported Viral Load or CD4 cell count.

## Primary Prevention



### A Randomized Clinical Trial of the Efficacy of a Behavioral Intervention to Prevent Acquisition of HIV Among Men who have Sex with Men (Project EXPLORE)

Project Staff: Tom Coates, Ph.D., PI; Margaret Chesney, Ph.D., Co-PI; Beryl Koblin (New York Blood Center), Ph.D., Co-PI; Patrick Barresi, MPH, Project Director; Kevin Filocamo, Project Assistant; Cliff Leonardi, MA, Project Assistant; Matthew Troy, Project Assistant; Mateo Rutherford, MS, Project Assistant

**Project Description:** This is a Phase IIb randomized controlled, proof of concept trial, which will assess the efficacy of a behavioral intervention vs. the standard risk reduction counseling to prevent HIV infection among men who have sex with men. The behavioral intervention consists of ten sessions over a four-month period followed by quarterly maintenance sessions. The control condition consists of semi-annual risk reduction counseling based on the Centers for Disease Control and Prevention (CDC)/Project RESPECT model for HIV pre- and post-test counseling. The trial has enrolled 4,294 MSM recruited at sites in Boston, Chicago, Denver, New York, San Francisco and Seattle study sites. The participants will be followed for three years. The seroincidence rate of HIV infection will be compared between the two arms of the study at the end of the three-year period.

**Significance:** Data from the HIVNET Vaccine Preparedness Study (VPS) have shown that brief (less than one-hour), didactic, one-session HIV risk reduction counseling in which HIV test results are discussed is not sufficient to change behavior. On the other hand, recent reports from the Project RESPECT I study suggest that two or four individual, participant-centered counseling sessions, such as those to be studied in this trial, can lower HIV and STD infection rates among heterosexual patients being tested and treated for STDs. This study extends these positive findings to a higher risk sample of MSM, and focuses on a number of risk reduction targets, including condom use, sexual behaviors in the context of alcohol or drug use, and sexual behaviors in the context of different types of partners and relationships. It also looks at communication skills, where participants meet their sexual partners, and how thoughts and feelings may influence their risk-taking.

The number of participants in each arm who become HIV-infected will be the end-point measure. This is the first time that a biological endpoint will be used to test the efficacy of a behavioral intervention.



## The Legacy Project: Lessons from a Collaborative Community-Based Organization/ Academic Research Partnership

Project Staff: Ellen Goldstein, Beth Freedman, Olga Grinstead, Anne Richards

**Project Description:** The Legacy Project analyzed 18 research studies collaboratively conducted by Bay Area community-based organizations and researchers at the Center for AIDS Prevention Studies. The goal of the analysis was to determine which elements of these collaborative projects contributed to successfully answering the Community Based Organization (CBO)-initiated research question and to building ongoing capacity within the CBO to conduct research and use research findings. These research projects were conducted within two consortia during 1994-1996 and 1997-1999.

Populations served by these 18 programs included school and street-based youth, gay men, Latina immigrant women, inmates and their female visitors, and substance users. The interventions included improvisational theater, peer education, multiple session groups, and social support and life skills education sessions. Projects conducted theory development as well as formative, descriptive and outcome studies. Both quantitative and qualitative data were collected.

The Legacy Project team reviewed collaboration documents and conducted interviews to answer the research questions.

**Significance:** Collaborative research between researchers and CBOs is becoming increasingly important. More and more, CBOs are required to evaluate the programs they offer, yet may not have the resources to conduct such an evaluation. Collaborative research also teaches researchers about community experience and program needs. As CBOs and researchers answer the call to engage in collaborative research partnerships, The Legacy Project findings can help to guide the research projects in order to optimize the experience and the outcomes.

**Interesting Findings:** Community-based collaborative research works. Fourteen of the 18 projects successfully answered a primary or secondary research question. Of the 16 agencies assessed for capacity, 12 were successful in improving their skills. Every individual who was a CBO partner in the collaboration, whether they remained at the same CBO or not, reported an increase in his or her ability to conduct and use research.

It is important to choose the level of evaluation that best suits the program and CBO capabilities. Feasibility and modification needs of new interventions make them poor candidates for outcome evaluation; trying to launch a new intervention while simultaneously evaluating it wasn't successful. Descriptive and formative studies were more appropriate research options for new interventions.

CBO stability and experience was positively correlated with successfully answering a research question. For CBOs without experience, beginning with less complicated research is a good way to develop skills. Also, attending to staffing and staff turnover is important when fielding research at a CBO.

It is important that the university researcher act as a full partner rather than a distant consultant for the collaborative research project to be successful. Meeting at the CBO and working with more CBO staff supported the collaboration and the science.

Including multiple research questions improved the likelihood that the project team generated useful findings from their research.

These consortia were labor and time intensive. Adequate resources for intervention, evaluation and participant time were necessary.



## Replicating the Mpowerment Project: Helping CBOs put prevention science into practice

Project Staff: Susan Kegeles, Ph.D.; Greg Rebchook, Ph.D.; Robert Hays, Ph.D.; Scott Tebbetts; Brady Ralston; Ben Zovod

**Project Description:** Many community-based HIV prevention programs are responding to high levels of HIV risk taking behavior among young gay/bisexual men by implementing community-level interventions. Additionally, funders are now encouraging HIV prevention providers to implement programs with demonstrated effectiveness. The Mpowerment Project is one such intervention. In order to help local HIV prevention providers tailor the intervention to the unique needs of their own communities, we have collaborated with CBOs to develop a replication package including: 1) an *Overview Video*, a 22-minute video presenting an overview of the project's philosophy, components and effectiveness, with testimonials by project participants; 2) a *Program Manual* providing background information and detailed guidance to implement each component of the Mpowerment Project; 3) an *M-group Facilitator Guide*, providing step-by-step instructions for running M-groups, and 4) a *Facilitator Training Video*, a 45-minute tape depicting a simulated M-group in action with narrator comments that highlight important tips in facilitating an M-group. Additionally, we collaborated with a California CBO to study the effectiveness of the replication package as they implemented the Mpowerment Project. We also are collaborating with the California STD/HIV Prevention Training Center to provide a comprehensive training program on the Mpowerment Project. We are seeking funding to finalize our package so that it is more user-friendly, including putting it on the web in such a way that it is easily downloaded by CBOs. We are also seeking funding to widely disseminate our replication package, expand our training efforts, and provide on-going technical assistance and capacity building for CBOs wishing to implement the Mpowerment Project.

**Significance:** Substantial research effort has gone into developing and evaluating HIV prevention interventions that are based on current theories of behavior change, utilize rigorous research designs, and focus on groups at high risk for HIV. As researchers who have spent the past ten years developing and evaluating the effectiveness of a model HIV prevention intervention program for young gay/bisexual men, we have contributed to this effort. However, despite the progress that we and other scientists have made in developing HIV prevention programs that are scientifically proven to be effective, critical questions remain regarding how such research can be put into practice by community-based HIV prevention providers. This replication project hopes to answer many of these questions.

**Interesting Findings:** 1) *The Mpowerment Project can be successfully replicated in a variety of diverse communities.* Projects from all across the U.S. are now implementing the Mpowerment Project with great success. Many of these programs have received assistance from CAPS to develop their interventions, and have received local or national funding for the Mpowerment Project. 2) *The Replication Package helps CBOs plan, tailor/adapt, and implement the Mpowerment Project in their communities.* Currently, we have distributed over 100 replication packages to HIV prevention providers both nationally and internationally. We have draft versions of our training manual and small groups facilitators guide posted on-line (hard copies are also available). 3) *Training on the Mpowerment Project is available and beneficial.* We have developed a comprehensive 3-day training for community-based HIV prevention providers who want to learn more about the Mpowerment Model. Several agencies who have participated in the training have subsequently written successful grants to implement the project in their communities. 4) *The Mpowerment Project developers are available to provide technical assistance to community-based HIV prevention providers.* We have provided limited technical assistance on-site, over the telephone, via e-mail, and through a web-based e-group which provides an electronic forum for those interested in



## Developing appropriate strategies to evaluate the Mpowerment Project at CBOs

Project Staff: Susan Kegeles, Ph.D.; Greg Rebchook, Ph.D.; Robert Hays, Ph.D.; Scott Tebbetts

Project Description: To gain a more comprehensive understanding of “real world” program evaluation, this project examined attitudes about evaluation, as well as evaluation methods from the perspectives of community based organizations (CBOs), funders, and evaluation professionals who provide technical assistance (TA).

Significance: Many effective HIV prevention programs have been developed through rigorous scientific research. As suggested by the CDC, many CBOs and health departments throughout the U.S. are beginning to implement HIV prevention programs with proven effectiveness. Numerous issues exist about moving programs from science into practice. One unresolved issue is how CBOs can meet the evaluation requirements established by their funders, since scientific evaluation methods used to establish an intervention’s effectiveness are beyond the capacity and funding levels of most CBOs. As scientists with funding from NIH, we have been able to conduct sophisticated and rigorous evaluation of the Mpowerment Project; however, the methods that we have used are complex, time-consuming, and expensive (e.g., lengthy randomized controlled trials with large, longitudinal samples). Indeed our evaluation procedures were much more costly than the intervention program itself. When CBOs implement our program, clearly they cannot use the methods we have used so far. Yet there is a lack of appropriate methods that they can use to evaluate their implementation of the Mpowerment Project or any other community-level interventions. As increasing numbers of CBOs are expressing interest in implementing the Mpowerment Project, it is critical that we are able to offer them evaluation methods that are feasible within the context and resources of a CBO and user-friendly for CBOs of varying capacities, i.e., easy, inexpensive, not disruptive to the organization, can be used relatively quickly, and are acceptable to the staff.

Interesting Findings: We conducted semi-structured interviews with 22 CBOs, 13 funders and 8 TA providers. CBO interviews assessed the types of process and outcome measures CBOs use to evaluate community-level interventions. Funder interviews assessed preferences and requirements funders have regarding evaluation methodologies. TA provider interviews helped establish evaluation recommendations regarding feasible and effective evaluation strategies that CBOs can implement. A number of important themes emerged in this research: 1) CBOs, funders and TA providers misunderstand each others’ expectations and capacities and do not collaborate optimally; 2) For CBOs, evaluation is often seen as an irritating, bothersome task, imposed by outsiders, which results in fewer resources for the most important task of CBOs, that of providing services; 3) Larger, better funded CBOs, and those with staff with training or skills in evaluation however, recognize the benefits to their organizations of doing good evaluation; 4) TA providers should strive to increase CBOs’ capacity to conduct evaluations; 5) funders need to have realistic expectations of what can be done by CBOs, and to make these expectations clear to organizations they fund. Based on these results, we developed a LOGIC Model that CBOs can use to evaluate Mpowerment. This Model provides a basic overview of the Mpowerment project, and it suggests beginning, interim, and ongoing activities, as well as the outcomes of the activities and evaluation tools for CBOs to use.



## Exploring the Cultural and Social Context of HIV Risk among Filipinos in San Francisco

Project Staff: Don Operario (PI), Victor Hall, Executive Director, Filipino Task Force on AIDS (consultant)

Project Description: Filipinos living in the U.S. constitute the largest number of reported AIDS cases among all Asian and Pacific Islanders (APIs). Unique social, psychological, and cultural factors potentially underlie the concentration of AIDS cases among Filipinos in the U.S. relative to other API groups. For example, stigmas and attitudes surrounding ethnicity, acculturation, sexuality, and gender roles can influence HIV-risk behaviors among Filipinos. Investigation of these factors is vital for the development of theory and interventions that target this growing population.

This proposal describes a pilot study aiming to:

- Examine culturally-embedded stigmas and attitudes related to HIV-risk behavior among Filipinos in San Francisco.
- Identify social and psychological factors that can be targeted in future research and in interventions, particularly factors that either amplify or diminish risk for HIV infection among members of target population.

The study will be conducted in collaboration with the Filipino Task Force on AIDS (FTFA), a community-based organization that has been providing services to the San Francisco community since 1988.

Significance: The Filipino population in the US remains an overlooked and understudied group, despite recent trends indicating large growth in size. Filipinos tend to be aggregated within the API umbrella, thereby masking unique social, cultural, historical forces that influence Filipino health. The significant rate of HIV within the Filipino community, particularly in comparison with other API groups, suggests increased research must address social and behavioral factors that render this group vulnerable to HIV. Prevention efforts must begin immediately in order to curb further spread of HIV within this growing population.

In collaboration with the Filipino Task Force on AIDS, we are conducting in-depth focus groups with 3 Filipino sub-populations: Men who have sex with men, recent immigrants, and youth. We will convene a total of 6 focus groups (2 per sub-population).

Interesting Findings: Data collection is currently in progress. Preliminary findings suggest that sexuality, sexual behavior, and HIV are extremely stigmatized issues within the larger Filipino community. HIV knowledge among recent immigrants and non-MSM youth is fairly low. Many participants state that the Filipino community considers itself relatively insulated from HIV. Families tend not to discuss issues surrounding sexuality, and Catholicism underlies some of this tension. Participants stated that stereotypes about and prejudice toward Filipinos abounds in the larger San Francisco community, particularly regarding some men's attitudes toward (and preferences for) Filipino gay men and women. Because of cultural and historical forces, many Filipinos fulfill their groups' stereotype (e.g., gender and sexual roles) in the context of interracial relationships.

Strategies for new HIV prevention interventions are being discussed based on findings.



## HIV Risk Behaviors among Japanese Nationals Temporarily Staying in Hawaii

Project staff: Tooru Nemoto, Yasuharu Hidaka

Project description: This study, funded by the Japanese Foundation for AIDS Prevention, investigates drug use and HIV risk behaviors among Japanese nationals visiting or temporarily residing in Honolulu, Hawaii. We have conducted 150 survey interviews with Japanese tourists, students, and temporary workers. Participants self-administered a structured questionnaire that included measures of sexual behaviors, drug use behaviors, AIDS knowledge, attitudes toward condom use, and social and cultural factors related to HIV risk behaviors.

Significance: The results will be used to develop HIV prevention programs targeting Japanese who stay temporarily abroad, as well as Japanese who plan to visit or study abroad.

Interesting findings: Preliminary analysis of the data has revealed that 54.8% of the sample first used an illicit drug in Japan. This finding is contrary to a popularly held perception in Japan that Japanese people first experiment with drugs while visiting the United States. Also, among heterosexuals in the sample, 1/3 of the men did not always use condoms for vaginal sex with a primary partner in the past year; about half the women did not either. Currently, we are conducting further data analysis.

## Risk Behavior



### HIV Risk Behaviors among Transgenders of Color

Project Staff: Tooru Nemoto, Ph.D., JoAnne Keatley, MSW, Don Operario, Ph.D., Melenie Eleneke, Dee Lila Camenga, Anna Fernandez, Lally C. Adao

**Project Description:** This 3 year study investigates HIV risk and protective behaviors among male-to-female transgenders of color, including those of African-American, Asian & Pacific Islander, and Latina descent, who have engaged in commercial sex in San Francisco. The study will examine the relationships between injecting hormones and sharing equipment for both hormone and drug use. The study will also determine intervening factors such as cognitive, cultural, and socioeconomic factors, and describe their relationships with both HIV risk and protective variables. During the first year, preparations for the study were made, which included focus groups, mapping, training staff, and a pilot study. During the second and third years of the study, a total of 300 one-on-one survey interviews are being conducted.

**Significance:** After the completion of quantitative data collection, we will conduct data analysis and disseminate study findings through the consultant agencies and local and national AIDS service organizations. With this study, the groundwork will be laid for developing HIV prevention intervention programs targeting male-to-female transgenders of color.

#### Preliminary Focus Group Findings:

- Psychological and mental health issues were the most recurring themes across all ethnic groups, and these issues influenced risky behaviors such as commercial sex work and drug use.
- Commercial sex and drug use usually starts during adolescence or early adulthood, so interventions should particularly target transgender youth.
- Unprotected sex was more common with primary partners than with clients; however, clients will pay more to not use condoms during sex.
- Existing drug treatment and harm reduction programs are inadequate for the needs of TG clients; some programs discriminate against TG clients.
- Roughly half of the participants reported having supportive parents and family, and family support was associated with more self-esteem.
- Many participants found support from older TG mentors who assisted their gender transition process, so a TG mentorship program could benefit TG youth.
- Clinics distribute hormone pills but not shots; however, TGs prefer hormone shots because of more satisfying physical effects.
- Because existing TG resources are insufficient, TGs need to help themselves by helping each other. The TG community, in collaboration with CBOs, need to consistently demand for better resources and funding for TG programs.



## Improving Measurement of HIV-Risk among Latino Adolescents

Project Staff: Nancy Padian, Regina Otero-Sabogal, Art Reingold, Alexandra Minnis, Judy Quan

Project Description/Significance: Accurate techniques for measuring high-risk sexual and drug use behaviors are critical to the development of effective HIV prevention. Recent research that has examined ways to increase the validity of self-reported HIV risk behaviors suggests that increasing the anonymity of the interview situation through use of audio computer-assisted self-interviewing (ACASI) may decrease underreporting. No published studies have examined these issues among Latino youth. Further, no research has assessed how acculturation and language might influence the effects of survey administration mode on validity of self-report. Latinos represent the fastest growing ethnic group within California's adolescent population and account for a disproportionate number of sexually transmitted infections and pregnancy, both of which are biologic markers for HIV risk. Reliable information is needed to inform the development of culturally and developmentally appropriate prevention programs and services that maximize the use of existing resources, as well as increase the capacity and capability of institutions to be more responsive to this segment of the population. This project seeks to identify accurate and acceptable ways to measure high-risk sexual behavior among Latino adolescents, and, in particular, to examine how the willingness to report sensitive information may vary across data collection modes. Four hundred Latino adolescents aged 15-19 will be recruited from New Generation Health Center, a teen health clinic located in San Francisco's Mission District. Using a randomized, prospective crossover design, we will compare the prevalence of HIV risk behaviors reported through two survey administration modes: ACASI and traditional pencil and paper self-administered questionnaire. At baseline, participants will be randomized to complete their interview using one of these modes. Three months after baseline, participants will complete a second behavioral and epidemiologic risk assessment questionnaire administered using the opposite mode from that with which they used to complete their baseline questionnaire. The findings from this study will inform the design of future research projects aimed at identifying effective ways to prevent HIV infection among Latino youth.

## Risk Behavior



### Project ÒRE´

(ÒRE is a Yoruba [an African language] word meaning friends)

Project Staff: Peggy Dolcini Ph.D., PI; Gary Harper Ph.D., Joe Catania Ph.D., Jon Ellen MD, Gail Bolan MD and Nancy Adler Ph.D., Co-Investigators; Susan Watson MPH, Field Director; Anthony King, Research Assistant

Project Description: Project ÒRE´, also known as the Neighborhood Adolescent Crowd Study, is a longitudinal study of social networks and sexual behavior among African American adolescents in and around the Bevies Hunters Point neighborhood. The study focuses on the stability of cliques, interaction patterns, sexual and drug using behavior, and rates of chlamydia and gonorrhea. Cliques are important and understudied source of behavioral influence, and this study will provide information to assist in the development of future social group based interventions.

To date, 201 eligible youth and their clique-mates have been successfully recruited into the study. Participants are currently completing their fourth and final interview (70% are completed). The majority of interviews have been conducted at the project field office in Bayview Hunters Point.

An additional goal of this project is the development of a culturally relevant and theory-based intervention that could be delivered in the context of the friendship group. We have developed an HIV/STD half-day intervention that is based on the AIDS Risk Reduction Model (ARRM). This intervention is currently being pilot tested.

Significance: African American adolescents living in inner cities are vulnerable to the threat of HIV due to the higher prevalence of STDs/HIV in their communities. In San Francisco, adolescents in Bayview Hunters Point district have the highest rates of STD infection. Existing adolescent prevention programs focus on changing peer norms (and thus behavior), but little attention is given to the myriad of subgroups that exist in the adolescent population. Interventions are delivered to a group of adolescents as a whole, failing to utilize naturally occurring social groups as a vehicle for program implementation. Additionally, there is minimal research on structure, stability, or characteristics of adolescent cliques, which this study addresses.

Interesting Findings: We have found that African American adolescents living in the study community have longstanding friendships with same gender friends. Their friendship groups are stable and many intimacies are shared within the group. Youth discuss dating and sexual issues with their close friends, which highlights the fact that friendship groups may provide a good vehicle for sexually related interventions (Dolcini et al, under review). Strong gender differences emerge in how youth talk about dating and sex and these differences have implications for intervention as well (Harper et al, in preparation).

Youth in our sample engage in behaviors or are in circumstances that put them at risk for HIV//STD transmission. Eighty-six percent of our sample were sexually active at baseline, 56% have had more than one partner in the past year, and nearly 20% have been pregnant or impregnated someone. Although alcohol use with sex is not especially common, about 40% of youth report use of marijuana before sex. The majority of youth consider their most recent partner to be their main partner. Sixteen percent report that this partner has sex with someone besides them, five percent report this partner has a history of an STD, and 32% indicate that this partner has been in jail or juvenile hall. Sixty percent of youth report always using condoms with their most recent partner.



## A Qualitative Study of Cybersex and MSM's HIV Risk Behavior

Project Staff: Greg Rebchook, Ph.D.; Susan Kegeles, Ph.D.; Dr. Alberto Curotto

**Project Description:** We are conducting semi-structured, on-line interviews and focus groups with 164 Internet-using MSM to: a) explore the role of the Internet in MSM's sexual lives by describing how and why they use the Internet for sexual purposes (e.g., engaging in on-line sexually-oriented conversations, using the Internet to meet sexual partners, viewing sexually explicit Web sites); b) determine the characteristics of MSM who use the Internet for sexual purposes; and c) examine how MSM's attitudes and HIV risk behaviors are influenced by these on-line activities. Additionally, we will collect pilot data to assess the feasibility of using an Internet-based intervention to prevent HIV transmission.

**Significance:** Alarming numbers of MSM continue to engage in unprotected anal intercourse, putting themselves and others at significant risk for HIV infection or reinfection. MSM account for over one-quarter of all new HIV infections in the U.S. and more AIDS cases than any other group. Unprotected anal intercourse with serodiscordant or unknown partners remains common among MSM, and rates of HIV risk behavior are increasing. Also of concern is evidence that drug-resistant strains of HIV are being sexually transmitted from man to man.

From many reports, the Internet now supplements the role of bars, bath-houses, and sex clubs in the gay community by providing opportunities for MSM to socialize on-line. MSM can access gay-oriented websites for a wide variety of topics including: resources, education, health issues, pornography, etc. Some of these sites eroticize unprotected sex. Gay chat rooms provide opportunities for real-time communication in groups. These rooms are organized primarily by location or by special interest. Internet-using MSM can read personal profiles of each chat room participant to identify potential friends, sex partners, lovers, or partners for other relationships. Some of these chat rooms are also devoted to unprotected sex. Instant messaging and private chats provide opportunities for individual conversations that may result in the development and maintenance of relationships, "cyber-sex" (sexually explicit chat), and/or immediate or future in-person meetings. On-line personal ads can also be used to arrange in-person meetings.

Clearly, the Internet has created new opportunities for MSM to engage in a wide variety of sexual behaviors. An Internet study of 129 gay HIV-positive men in the San Francisco Bay Area who used AOL chat rooms found that 95% identified the Internet as their primary and preferred method of finding sexual partners. They routinely disclosed their HIV status to their partners, and they reported a variety of risk behaviors including high rates of using illicit drugs and nitrates during sex. In August 1999, at least eight male subscribers to AOL, all of whom reported multiple sex partners in the past two months, contracted syphilis from sex partners they met through gay-oriented, San Francisco Internet chat rooms, and three of the men also reported testing HIV-positive. This incident raises numerous questions about the role of cybersex in emerging patterns of HIV risk behavior, including "barebacking." However, little is known about how the widespread use of this technology may be affecting MSM's sexual behavior.

**Interesting Findings:** Since the project was only recently funded no data have been collected yet. Data collection is not scheduled to start until 3/01.



## Sexual History and Risky Sexual Behavior in Latino Gay Men

Project Staff: Sonya Grant Arreola, PhD, MPH; Barbara VanOss Marín, PhD; Rafael Diaz, PhD

Project Description: Thirty LGM between the ages of 20 and 40 will be recruited for individual 2-hour interviews that will be conducted by the PI at CAPS. Recruiters will be hired to recruit participants from social venues frequented by LGM, such as bars and sex clubs. Participants will be assessed for history of childhood sexual abuse (CSA) and current sexual activity. Participants will be eligible if they are: Latino, between 20 and 40 years old, self identify as gay or bisexual; and have had inconsistent condom use within last six months (at least 1 occurrence of anal sex with a condom and 1 without a condom). Ten participants will have had no history of CSA, 10 will have had a history of CSA without coercion, and 10 will have had a history of CSA with coercion. All interviews will be conducted in English and participants will be given \$50.00 as an incentive and reimbursement for their time. A list of referrals to support groups and treatment programs in the city will be given to all participants.

Interviews will be recorded, transcribed, and coded to assess history of CSA and different dimensions of current sexual contexts within both protected and unprotected sexual episodes.

Comparisons between protected and unprotected episodes will be made within the three CSA groups, and the relationships between CSA history and sexual episodes will be examined.

Significance: Multiple quantitative studies show that childhood sexual abuse (CSA) is a strong predictor of risk for HIV infection (Bartholow et al, 1994; Jinich et al 1998; Paul et al 1994). However, why this relationship exists is not known. This project is the first step in a larger research agenda toward understanding the mechanisms that explain this relationship. The goal of the present project is to qualitatively explore the relationships between CSA and risky sexual behaviors among Latino gay men in San Francisco.



## STD Risks Associated with Adolescents' Sexual Networks (African American)

Project Staff: Nancy Padian, Steve Shiboski, Peggy Dolcini, Jonathan Ellen, Richard Rothenberg, Thomas Piazza, John Sieverding, Beth Brown, Sarah Glass, Loreen Hanak

Project Description/Significance: No studies have directly examined the role of social and sexual networks in maintaining the high rates of sexually transmitted diseases (STDs) among African-American adolescents. The goal of the proposed five-year longitudinal study is to develop a better understanding of the role of social and sexual networks in maintaining the high prevalence of STDs among African-American adolescents residing in the Bayview-Hunters' point area of San Francisco. We will accomplish this by interviewing a random digit telephone sample of African-American adolescents, 14-19 years old, residing in San Francisco, CA and testing them for STDs. In addition, we will recruit and interview their sex partners in order to characterize the index adolescents' social and sexual networks. Ultimately, the findings of this study may permit public health programs to focus part of their resources on those individuals who are essential to the spread of STDs, and by doing so, quickly and cost-effectively, slow the spread of STDs among adolescents. Specifically, our goals are:

- To determine the association between the characteristics of adolescents' social and sexual networks and the incidence and prevalence of STDs among 240 African American adolescents in the San Francisco metropolitan area over a two year time period
- To determine behavioral and developmental factors associated with membership in STD risk-related social and sexual networks among 240 African American adolescents in the San Francisco metropolitan area over a two-year time
- To determine the accuracy of adolescents' perception of risk for STDs by comparing their risk perceptions to the their proximity to or membership in STD risk-related social and sexual networks among 240 African American adolescents in the San Francisco metropolitan area over a two year time period.
- To determine behavioral and developmental factors associated with membership in STD risk-related social and sexual networks among African American adolescents in the San Francisco metropolitan area who have recently become sexually active.

## Risk Behavior



### Improving Measurement of HIV-Risk among Latino Adolescents

Project Staff: Nancy Padian, Regina Otero-Sabogal, Art Reingold, Alexandra Minnis, Judy Quan

Project Description/Significance: Accurate techniques for measuring high-risk sexual and drug use behaviors are critical to the development of effective HIV prevention. Recent research that has examined ways to increase the validity of self-reported HIV risk behaviors suggests that increasing the anonymity of the interview situation through use of audio computer-assisted self-interviewing (ACASI) may decrease underreporting. No published studies have examined these issues among Latino youth. Further, no research has assessed how acculturation and language might influence the effects of survey administration mode on validity of self-report. Latinos represent the fastest growing ethnic group within California's adolescent population and account for a disproportionate number of sexually transmitted infections and pregnancy, both of which are biologic markers for HIV risk. Reliable information is needed to inform the development of culturally and developmentally appropriate prevention programs and services that maximize the use of existing resources, as well as increase the capacity and capability of institutions to be more responsive to this segment of the population. This project seeks to identify accurate and acceptable ways to measure high-risk sexual behavior among Latino adolescents, and, in particular, to examine how the willingness to report sensitive information may vary across data collection modes. Four hundred Latino adolescents aged 15-19 will be recruited from New Generation Health Center, a teen health clinic located in San Francisco's Mission District. Using a randomized, prospective crossover design, we will compare the prevalence of HIV risk behaviors reported through two survey administration modes: ACASI and traditional pencil and paper self-administered questionnaire. At baseline, participants will be randomized to complete their interview using one of these modes. Three months after baseline, participants will complete a second behavioral and epidemiologic risk assessment questionnaire administered using the opposite mode from that with which they used to complete their baseline questionnaire. The findings from this study will inform the design of future research projects aimed at identifying effective ways to prevent HIV infection among Latino youth.



## Methamphetamine Dependence and the Risk of HIV Infection

Project Staff: Gantt Galloway, David R. Gibson, Neil M. Flynn

**Project Description:** The project is following a cohort of methamphetamine users, half of whom are entering drug treatment. The objectives are to study the natural history of methamphetamine addiction in relation to HIV risk behavior and seroincidence and psychiatric co-morbidity. We are also conducting magnetic resonance imaging (MRI) and spectroscopy (MRS) to evaluate the effect of methamphetamine on brain structure and function, and testing to determine whether paranoid psychosis associated with methamphetamine use may have a genetic basis.

**Significance:** This project is one of the first in-depth studies of users of methamphetamine, a drug whose use in recent years has spread from California to many other parts of the country.

**Interesting Findings:** Data collection is underway, and is expected to be completed by mid-2002.

## Smoking



### Determinants of Smoking among Gay and Lesbian Youth

Project Staff: Jay Paul (PI), Diane Binson, Greg Greenwood, John Servilio

**Project Description:** This qualitative study is examining the factors that lead to high rates of cigarette smoking among gay, lesbian, and bisexual youth. There are two stages to this research project. The first stage involves conducting a series of focus groups with gay-, lesbian-, and bisexually-identified 18- to 23-year old smokers in Los Angeles and San Francisco. We anticipate holding a total of 6 focus groups in each city, 2 male, 2 female, and 2 with both males and females. Respondents talk about their smoking history, factors that led to initiation of tobacco use (e.g., life experiences concurrent to the onset of cigarette use; functions of smoking behavior) and current factors that influence smoking (e.g., social norms, social/environmental contexts, activities, and social groups with whom they smoke; the meanings given to smoking behavior; perceived health risks; attitudes with respect to smokers vs. non-smokers). From this process, we are exploring what, if any, gay-specific variables may influence the initiation of smoking or maintain smoking behaviors.

The focus group data provides a framework for further exploration of evolving themes and concepts in the second stage of this study, involving in-depth individual interviews of 72 gay/lesbian/bisexual 18- to 23-year old smokers in San Francisco. Themes and concepts identified by focus group data will be the basis of the creation of an open-ended interview schedule. We will also conduct some interviews with non-smoking gay/lesbian/bisexual young adults to test some of the emerging notions about what influences are most significant to a smoking career in this population. A theoretical sampling frame guides this recruitment process to ensure diversity of respondents, along the following dimensions: gender, educational attainment, and race/ethnicity. These interviews will provide an opportunity to gain more in-depth information on the smoking histories of younger gay and lesbian smokers. We will explore a variety of variables that have been previously linked to smoking initiation, as well as keeping the structure of the interview open enough to permit new concepts to emerge.

**Significance:** After years of steady declines in rates of use, cigarette smoking may be on the rise among adolescents and young adults. Prior work has demonstrated that tobacco use is more prevalent among gay and bisexual men than among the general population. Other research findings suggest that this is also true for lesbians and bisexual women, in comparison to their general population counterparts. Our prior research has also suggested that these higher rates of smoking are potentially determined by some gay-specific factors. However, we have little information on the determinants of smoking behavior and the specific appeal of cigarettes for gay youth. This hampers our ability to design effective and appropriate prevention campaigns or smoking cessation programs for this population. The results of this study will be used to inform interventions that target gay and lesbian youth to a) reduce the numbers of such youth who initiate smoking, b) address the contexts in which those who have initiated smoking may progress to regular smoking (and addiction), and c) provide appropriate smoking cessation programs.

**Interesting Findings:** We are just starting to examine the focus group data (having completed 6 of 12 planned groups), and thus cannot provide any clear findings to date. Early initial readings of the responses so far suggest that cigarettes may have a powerful attraction to GLB youth on a number of fronts, including the following. First, as a means of bonding with others (both those who may be also be gay, and those who are simply seen as "nonconformist"), which has a powerful impact on adolescents dealing with a sense of difference and awkwardness due to their sexual orientation. Second, as an easy and swift means of manipulating the image they project to others (in some cases, this relates to gender conformity) among youth who are terribly self-conscious of their sense of self as related to their sexual orientation. Third, as a means of experimenting with/reconstructing their self-identity, which is interwoven with their exploration of their sexual orientation.

## Smoking ❖❖❖

### Queer Tobacco Intervention Project (QueerTIP)

Project Staff: Greg Greenwood (CAPS), Carolyn Hunt (PRTA), Darlene deManincor (CAPS), Brady Ralston (CAPS), Joe Ereneta (LYRIC), Bob Gordon (SF Tobacco Free Project), Liz Gruskin (Lyon-Martin), Gary Humfleet (UCSF), Dominique Leslie (PRTA Consultant), Yosenio Lewis (LLEGO), Joe Neisen (New Leaf), Jay Paul (CAPS), Steven Rickards (ACS), Bethsaida Ruiz (PRTA), Gloria Soliz (CLASH)

**Project Description:** We are a community-academic collaborative 1-year pilot project funded by the California Tobacco-Related Disease Research Program. We are designing and evaluating culturally-specific smoking cessation services targeted to Lesbian, Gay, Bisexual and Transgender (LGBT) adult and youth. Our first step was to conduct a needs assessment survey. We hosted a smoking cessation group for lesbian and bisexual women only at Lyon-Martin. We are designing a queer-specific smoking cessation program to be pilot tested at New Leaf among their clients. In collaboration with the American Cancer Society (ACS), we are also training and certifying a number of LGBT persons to be smoking cessation group leaders for QueerTIP and ACS. We are working with LYRIC and the SF Tobacco Free Project to conduct outreach and education activities among youth attending a number of LGBT-specific youth events. We are also working with local and national LGBT youth leaders and organizations to write and submit a proposal to the American Legacy Foundation to conduct formative work to develop smoking cessation services specifically by and for LGBTQ youth. Such work will also occur with LGBT adults to continue this pilot work.

**Significance:** Compared to the general population, cigarette smoking among the LGBT community is highly prevalent in this diverse and socially marginalized population, thus rendering this community at higher risk for tobacco-related problems. But treatment development and research of effective, culturally competent intervention services have not been conducted. Tobacco treatment research within the LGBT community has consistently fallen far short when compared with treatment development and research of LGBT-specific interventions for other health risks (e.g., alcohol and drug use, STD/HIV treatment and prevention). It is time to develop and examine the effectiveness of tobacco intervention services developed for and implemented specifically among the LGBT community.

**Interesting Findings:** Strong collaborative relationships continue to grow, and diverse segments of LGBT communities are starting to coalesce around this previously ignored public health problem. Many LGBT are not aware that tobacco use is a serious health problem among LGBT, or they do not see it as a priority in light of discrimination, homophobia, HIV/AIDS and other health issues facing LGBT. Part of the challenge we face is educating others about the disproportionate use of tobacco among LGBT, the added health burden, and the targeted marketing/sponsorship by tobacco companies.

## Smoking



### Tobacco Use Among Gay and Bisexual Men

Project Staff: Greg Greenwood, Diane Binson, Jay Paul, Lance Pollack, and Ron Stall

**Project Description:** The primary objective of this study is to examine the behavioral epidemiology of tobacco use among gay and bisexual men. Specific aims are: (1) To identify the prevalence of tobacco use among urban gay men. (2) To identify the psychosocial correlates of tobacco use among these men. (3) To determine whether rates of tobacco use are different among urban gay men who reside in California than in other urban centers of the United States. (4) To identify the perceived need among gay male smokers for gay-specific treatment approaches to smoking cessation. Tobacco surveys were administered to 1780 (of 2375) men who have sex with men (MSM) from the Urban Men's Health Study (Catania, PI). Telephone interviews occurred from January through December 1999. The Tobacco Survey lasted an average of 20 minutes and included questions on tobacco usage (both current and lifetime), attempts to quit smoking, and attitudes about smoking in relation to people and places.

**Significance:** The epidemiology of tobacco use among gay and bisexual men has been difficult to accurately gauge for two primary reasons: gay men's health studies have not researched tobacco use, and population-based epidemiological studies of tobacco have not asked about sexual orientation. In the most scientifically rigorous study to date, Stall and colleagues (1999) found that smoking rates among a combined household-based and bar-based sample of gay and bisexual men were substantially higher than a general sample of adult men. But these and previous estimates (Skinner, 1994; Skinner & Otis, 1996) of cigarette smoking among gay and bisexual men may have been inflated due to the opportunistic sampling methods used in these studies resulting in over-sampling of gay male smokers (i.e. through recruitment at gay bars). Estimating the prevalence of current smoking with data drawn from probabilistic sampling methods should be attempted before claims of higher current smoking rates among men who have sex with men (MSM) are accepted.

**Interesting Findings:** Preliminary estimates indicate that urban MSM smoke at higher rates than general samples of adult men living in the same four cities. Preliminary analyses suggest that gay men "most likely" to quit in the next year were those who saw smoking as a special health concern in the gay community, who felt that smoking made a person less attractive, who had an alcohol- or drug-abusing parent, and who were HIV-positive. Most smokers had tried to quit in the previous 5 years (primarily by efforts to cut down on their smoking over time), and a substantial proportion had tried to use nicotine supplements as adjuncts to their cessation efforts. Respondents were willing to try a variety of methods to quit in the future that they hadn't tried to date. Next steps include final data analysis, manuscript preparation and submission to peer-reviewed journals, and community dissemination of research findings. Prevalence and risk factor data will be disseminated to local, state, national and international professional audiences.



## The School Entry Study

Project Staff: Tom Boyce, MD, Principal Investigator, Margaret Chesney PhD and Diane Wara MD, Co-Investigators, Mary Truskier, RN, MS, Project Coordinator

Project Description: The School Entry Study is a five year, longitudinal examination of the early school adaptation of children living with HIV in the Bay Area. Four successive cohorts of five and six year old children have been studied as they entered elementary school. The HIV-positive and HIV-negative children of HIV-positive mothers have been compared to healthy age-mates born to uninfected mothers on measures of child and family characteristics, and contextual variables. We will illuminate the resources and limitations the children bring to their first experiences in elementary school. Their reactions to school entry stress are measured through behavioral markers as well as biologic changes in immune, cardiovascular and hormonal functioning.

Significance: With the advent of newer drug therapies, most HIV+ children are well enough to regularly attend school. Little has been written about their responses to the developmental and unique challenges they face at school age. With the recent large reduction in perinatal transmission, the number of HIV-negative children born to positive mothers has increased and will continue to increase. Preliminary data from the School Entry Project suggest that these negative children often bear a greater burden of poverty and maternal illness than even their HIV+ counterparts. This growing group constitutes a particularly vulnerable sub-population which is not well represented in research endeavors or service programs.

Interesting Findings: Videotaped interviews with each of the 133 children enrolled in the study contain some of the project's richest data. Using a newly developed technique, the Berkeley Puppet Interview, project staff elicited the childrens' self-perceptions regarding their social and academic experiences at school. Two puppy-dog puppets present a range of opinions and ideas the children are invited to endorse or deny. The results are revealing and fascinating. Data collection is now concluding, and final analyses are about to begin.



## Caregiving and Mental Health in Mothers of HIV+ Children

Project Staff: Susan Folkman, Ph.D. Principal Investigator; Judith Moskowitz, Ph.D. Co-Investigator, Project Director; Leslie Wilson, Ph.D. Co-Investigator, Project Health Economist; Melvin Heyman, M.D. Co-Investigator, Project Medical Director; Mike Acree, Ph.D. Senior Statistician; Eunice Dizon, Data Manager; Judith Wrubel, Ph.D. Qualitative Analyst; Anne Richards, M.A., Qualitative Analyst; Jenna Grant, Project Assistant; Paul Harmatz, M.D. Co-Investigator, Director Oakland Site; Steve Ferrando, M.D. Co-Investigator, Director New York Site;

Project Description: The Maternal Caregivers Study is a four-year tri-site study designed to explain the relationship between mental health and the stress of caregiving in mothers of children with HIV/AIDS and other chronic illnesses. We also want to estimate the economic costs of home care provided by maternal caregivers.

Maternal caregiver is defined as the woman who has the primary responsibility for looking after a child in the home. She could be the biological mother, other female kin, such as an aunt or grandmother, a foster mother or an adoptive mother.

We are interviewing maternal caregivers of three groups of children:

- children with HIV/AIDS (infected via perinatal transmission)
- children with chronic illnesses (such as Crohn's disease, sickle cell anemia, diabetes)
- and healthy children

Participation entails 3 interviews over a 6 month period. The interviews have qualitative and quantitative components and last about 3 hours. In San Francisco, the interviews will take place at the UCSF Pediatric Clinical Research Center, and in Oakland they will take place at the Children's Hospital Oakland Pediatric Clinical Research Center. In New York, the interviews will take place at the New York Presbyterian Hospital. At all sites interviews will be conducted in Spanish with caregivers for whom Spanish is the primary language. We provide child care and refreshments and will reimburse participants for parking and transportation costs. Participants are compensated \$50 for each interview.

Significance: There is scant information regarding the experience of maternal caregivers. We are interested in what caregivers actually do, e.g. what skills and responsibilities are involved, as well as what it means for each woman to be a caregiver. We ask about social, emotional and spiritual resources in our efforts to discover how women cope with the stress of caregiving.



## The CHANGES Project: A Clinical Trial of Coping Effectiveness Training in HIV-Infected Gay Men

Project Staff: Margaret Chesney, Principal Investigator; Susan Folkman, Co-Principal Investigator; Don Chambers, Co-Investigator; Joey Taylor, Project Manager; Tom Holt and Laurie Hessen, Clinical Supervisors; Brian Dietrich, Chaya Rivka Mayerson, Bettina O'Brien, and Joshua Schwartz, Group Facilitators; Neal Carnes, Recruitment Coordinator and Interviewer; Larry Lariosa and Sheri Storey, Interviewers.

Project Description: HIV infection can create profound psychological distress. Interventions are needed to help people living with HIV cope with their chronic and debilitating disease. The project's objective is to evaluate a coping intervention, Coping Effectiveness Training (CET), designed to assist HIV+ gay men in sustaining psychological health despite the ongoing stress associated with HIV infection. The study is a randomized clinical trial of an innovative, theory-based coping intervention. The research questions address the important problems of maintaining intervention effects, evaluating intervention effects on quality of life, health care utilization and adherence to medical care, and testing new advances in stress and coping theory. Approximately 200 HIV+ gay men in the Bay Area enrolled and are assessed at baseline and 3-, 6-, and 12-month followup.

Significance: The evaluation of CET addresses the crucial need for proven interventions to help HIV-infected people cope with the chronic and debilitating aspects of their disease. It also addresses the need for clinically relevant data to establish guidelines for mental health care. Helping HIV+ people to reduce stress and adhere to their medical care may in turn help to reduce their risky behavior. In this sense, "HIV prevention" is not just about preventing viral transmission, but also about preventing disease progression and the mental health consequences of HIV. In addition, the study provides a setting to test new advances in stress and coping theory, and its findings will extend to people living with other chronic diseases, their caregivers and health care providers.

Interesting Findings: The issue of side effects and symptoms, particularly fatigue, has emerged as a major topic in relationship to adherence to HIV care and continuation in medical treatment. In fact, a central challenge in HIV clinical trials and treatment is medication "burnout" from patients struggling to manage HIV's intrusions on their quality of life. That 87.5% of our CHANGES Project participants report at least some level of fatigue underscores the importance of this problem. Relationships between fatigue and our measures of psychological distress and quality of life demonstrate inverse associations between fatigue and a number of important facets of adaptive psychological functioning. These relationships strongly suggest the need and begin to suggest direction for interventions related to fatigue management.

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