BAY AREA CONSORTIUM FOR QUALITY HEALTH CARE

ADVANCING SOLUTIONS IN WOMEN'S HEALTH

– Grant Template –

October 2006

RESEARCH PROGRAM

NEW METHODOLOGIES IN TREATMENT & REDUCTION OF SEXUALLY TRANSMITTED INFECTIONS

ABSTRACT

Bay Area Consortium for Quality Health Care (Consortium), a leading women's health organization in Northern California, will collaborate with the University of California at Berkeley and San Francisco, Holy Names University, Children's Hospital Oakland, Providing Alternatives to Violence, and the California Board of Registered Nursing, to implement a research initiative entitled, *New Methodologies in Treatment & Reduction of Sexually Transmitted Infections (New Methodologies)*. Based on prevalent research correlating women's exposure to violence and increased risks for sexually transmitted infections (STI), this initiative will investigate innovative methodologies in treatment and intervention. Researchers will examine the impact of treatment for stress-related conditions caused by violent experiences and the impact of violence prevention training on STI treatment adherence and recurrence.

The goal of this initiative is to reduce STI recurrence while also reducing women's risk factors for continued exposure to violence. Researchers will target a multi-generational cohort of women and girls and integrate factors of demographics, types of abuse, socio-economics and behavior into data collection and analysis.

The methodological approach is three-fold:

(1) Researchers will test the hypothesis that treating women for stress conditions related to violence (including PTSD), and training them in violence prevention will improve their STI treatment adherence and also reduce their rates of STI recurrence;

(2) Collaborators from multiple disciplines will create an intervention model through culturally specific violence prevention training. Based on the Consortium's staffing capacity to provide services in eight different languages and its unique approach in multi-generational program delivery, this model will integrate the dynamics of culture, age and gender; and

(3) Through collaboration with the California Board of Registered Nursing and Holy Names University, partners will build upon research findings to develop and pilot a statewide, professional development curriculum to train health providers to expertly address ethnicity and gender/sex role factors in STI treatment and treatment adherence.

Consequently, the successful implementation of the *New Methodologies* initiative will prospectively demonstrate statewide significance through the following objectives:

***NEW METHODOLOGIES* - RESEARCH PROGRAM OBJECTIVES:**

1. **Determine the intervention effectiveness of post violence treatment and violence prevention training on reducing STI recurrence;**

2. **Determine the impact of treatment for stress related disorders on STI treatment adherence and recurrence;**

3. **Identify emerging practices in health care delivery, which will lead to better identification and assistance of women with PTSD or other stress related disorders on STI treatment adherence. Researchers will measure cortisol levels to diagnose and track stress responses.** Oftentimes, in clinical practice, these women are not identified or treated for symptoms, constituting a potential, critical barrier to success in the field of STI prevention;

4. **Investigate cultural and situation-based antecedents of health disparities for women through review of STI risk factors for teen girls; and**

5. **Establish replicable guidelines for efficient health care delivery that more effectively prevents STI recurrence for low-income women.**

The research of *New Methodologies* will target the Consortium's exceptionally diverse client base of underserved, uninsured, and low-income women from four clinic sites across three public health jurisdictions in Northern California: Alameda County, San Francisco County and the City of Berkeley.

NEED STATEMENT

Target Service Area 1 - Alameda County

The Bay Area Consortium for Quality Health Care's main geographic service delivery area is the region of Alameda County (population 1.4 million) with specific emphasis on the City of Oakland and its bordering cities. Alameda County has the second largest number of African Americans in the State of California. It is the fifth most ethnically diverse county in the United States, with ethnic demographics of 53% White, 17% African American, 14% Asian American, 12% Latino, and 5% Native American. As the eighth largest city in California, Oakland is one of the most ethnically-diverse cities in the nation; African Americans constitute 44% of the population, Whites—32.4%, Asians/Pacific Islanders—15%, Hispanic—14%, and other—9%. Oakland citizens speak at least 81 languages and dialects. The city has a poverty rate of 18.5% (68,871 people), compared to 8.3% countrywide, and 12.5% statewide.

The city's overall unemployment rate is 8.1%, which is considerably higher than the county's and state's. Teenage unemployment is especially high. One in four teens out of school and not in the labor force is unemployed. In some areas of Oakland, nearly all out-of-school youth are jobless, regardless of their high school graduation status. Oakland's public school system is significantly challenged. Its 52,000 students are 90% children of color. Nearly 25% of the students are not fluent in English, and almost 50% are on public assistance. These facts exacerbate the risk factors contributing to a myriad of health and social service problems.

In addition to clinics and offices in Oakland, the Consortium provides services in cities of Berkeley and San Francisco.

Target Service Area 2 – City of Berkeley

While the City of Berkeley is within Alameda County, it maintains a completely independent health service division from the Alameda County Public Health Department. As one of only three cities in the State of California with the distinction of having its own health jurisdiction, the Berkeley Public Health Division is dedicated to ensuring the health and well being of Berkeley residents specifically.

With a population of 102,743 residents (2000 Census), the City of Berkeley is one of the most densely populated communities in the state, with 107,800 residents living in approximately 10 square miles. Additionally, Berkeley's diverse population is characterized by significant economic, educational, social and racial disparities, which are reflected in various indicators of health and quality of life. According to the 1998 population estimates, the city's residents are 54% White, 19% African American, 15% Asian/Pacific Islander and 10% Latino. According to the 1990 Census, the largest Asian ethnic groups were Chinese, Japanese, Filipino, Korean and Asian Indian and Vietnamese. Nearly 60% of the Latino population was of Mexican descent.

African American and Latino communities are concentrated primarily in the low-income areas of South and West Berkeley. In 1990, nearly half (47.4%) the population below 200% of poverty resided in South and West Berkeley and three out of four children below poverty (76%) lived in these areas. Roughly 3/4 of those eligible for MediCal and people on Temporary Assistance to Needy Families (76%) reside in South and West Berkeley.

In the area of domestic violence, 1,830 domestic violence physical and related non-physical incident reports were filed with the Berkeley Police Department, Domestic Violence Prevention Unit in 1997-98. Women were named as the victim in 84% of the cases and the perpetrator was arrested in 29% of the cases.

Target Service Area 3 – City & County of San Francisco

Based on the 2000 Census, the city's ethnic demographics comprise 43.6% White, 30.7% Asian Pacific Islander American, 14% Hispanic, 7.6% African Americans, and 0.3% American Indian.

According to the 2000 Census, 56.4% of the City's population is identified as being composed of minorities, and therefore any census tract in which 76.4% of the population is classified as minority would qualify as an Area of Minority Concentration. Using this figure, San Francisco has a total of 45 census tracts that meet the definition of Minority Concentration. Add any available SF data

Can insert local violence prevalence data if wish (for 3 jurisdictions)

Sexually Transmitted Infections

It is estimated that more than 15 million new cases of sexually transmitted infections are diagnosed each year in the United States (Cates, 1999) — Approximately one-fourth of these new infections occur among teenagers (CDC, 2000a). By the age of 24, one in three sexually active people will have contracted an STI (KFF, 1998b); moreover, at least one in four Americans — perhaps as many as one in two — will contract an STI at some point in their lives (AGI, 1993). In total, At least 65 million people — more than one in five Americans — are believed to be infected with a viral STI other than HIV (NCHSTP, [1999]).

California Prevalence Rates: In California, rates of chlamydia, gonorrhea, and early syphilis all increased in 2004, compared to 2003.[i] In 2004, nearly 123,000 cases of chlamydia were reported (122,538 cases, for a rate of 334.9 per 100,000 population); approximately 30,000 cases of gonorrhea were reported (30,258 cases, for a rate of 82.7 per 100,000 population); and nearly 1,400 cases of primary and secondary syphilis were reported (1,358 cases, for a rate of 3.7 per 100,000 population). These large numbers of reported cases made sexually transmitted infections the most commonly reported communicable diseases in California (and in the United States). These increases in chlamydia, gonorrhea, and syphilis in 2004 were generally seen in all age groups, in all race/ethnic groups, and in both males and females. One notable trend was that syphilis increased slightly again in females from 0.3 in 2003 to 0.4 in 2004, after steady decreases since 1990.[ii]

Many important patterns (e.g., geography, sex, age, race/ethnicity, time) of STI distribution are key notable points that demonstrate disturbing patterns: the extraordinarily high rates of STIs among African Americans and the high rates of chlamydia and gonorrhea among persons under 25 years of age, particularly females. For example, the gonorrhea rate in 2004 for African American females was more than 12 times higher than for non-Latina white females. Also of concern is the large number of STIs among young persons, patterns observed in case-based reporting data, as well as in prevalence monitoring data from public and private sector sentinel sites. For example, in 2004, more than 60,000 cases of chlamydia in females (ages 15 to 24 years) were reported, representing almost 70% of all female cases. Secondly, when case incidence was calculated for these females, Alameda County (607.6) was the jurisdiction with the second highest incidence of gonorrhea following Sacramento (702.1).[iii]

Women & STIs: Sexually transmitted infections are exacting a disproportionately heavy toll among impoverished, young women, especially women of color. The presence of sexually transmitted infections in this population is a harbinger for further morbidity, such as infertility and HIV infection. AIDS is now the third leading cause of death in women aged 25 to 44 in the United States.[iv] Further, it is the leading cause of death in African American women in this age group. A study by Ruiz et al[v] confirms the higher prevalence of sexually transmitted infection and HIV among women with low incomes, predominantly from ethnic minorities, in Northern California. The authors report a disturbing rate of HSV-2[1] infection and a prevalence of HIV infection that is 4 times the estimate for other women in California.

Perhaps most concerning, the study shows that these women have an alarming rate of unprotected sexual contact with men at high risk for HIV and sexually transmitted infections. Many studies have addressed why these women are exposed to such risks.[vi][vii] Women frequently have difficulty negotiating safe sex and the use of condoms with their partners. For women who do not use condoms, many times there is a power imbalance in their intimate relationships threatening their sense of personal safety. Many women experience anger and violence from their partners when they suggest condom use. Further, women who are financially dependent on their partners may feel powerless to insist on condom use. Finally, judgment may be impaired under the influence of drugs or alcohol; essentially, a high percentage of women reported being intoxicated during sex.

These circumstances present exceptional challenges for primary care physicians when the epidemic of sexually transmitted infection in women is viewed as a social problem—poverty, violence, substance misuse, ignorance, and relative powerlessness—and is often at the root of transmission. The prevention of the transmission is more challenging than treatment.

[1] Herpes simplex virus 2

Nationally, clinics report women as maintaining higher contraction rates for many STIs as compared to men.

Reported cases of STI by sex and reporting source: United States, 2004

	Non-STD Clinic			STD Clinic			Total *		
Disease	*Male*	*Female*	*Total*	*Male*	*Female*	*Total*	*Male*	*Female*	*Total*
Chlamydia	128,209	588,112	717,732	73,948	94,197	168,318	210,396	716,675	929,462
Gonorrhea	83,335	131,392	215,113	67,106	30,832	97,988	157,303	172,142	330,132
Primary Syphilis	1,117	132	1,249	883	109	993	2,026	241	2,269
Secondary Syphilis	3,257	630	3,888	1,361	368	1,729	4,696	1,014	5,711
Early Latent Syphilis	3,484	1,426	4,912	1,852	877	2,731	5,433	2,331	7,768
Late and Late Latent Syphilis †	7,105	4,689	11,839	3,058	2,095	5,171	10,340	6,896	17,300
Neurosyphilis	552	143	695	84	33	117	650	182	833
Chancroid	10	7	17	8	1	9	19	9	30

*Totals include unknown sex and reporting source.

†Late and late latent syphilis includes cases of unknown duration, late syphilis with clinical manifestations, and neurosyphilis.

The Threat to Women's Health

Sexually transmitted infections (STIs) for women are typically transmitted by unprotected sexual contact. The most common diseases that are transmitted sexually are chlamydia, genital herpes, genital warts, gonorrhea, hepatitis B, HPV[2], HIV/AIDS, and syphilis. Women account for about half of all sexually transmitted infections that occur each year, but they suffer more frequent and severe long-term consequences than men (AGI, 1993). Women are more severely affected because they are physiologically more susceptible to infection and less likely to experience symptoms, which make detection more difficult until serious problems develop (DSTDP, 1998; KFF, 1998b).

Early identification and treatment is very important to prevent complications and the spread of infection to other people. Women who are not treated or whose treatment is delayed may get pelvic inflammatory disease (PID), which can result in infertility or ectopic pregnancy[viii]. Infected women can transmit an STI to their offspring during pregnancy and childbirth, or after birth. The results can be devastating — STI infections can cause spontaneous abortion, stillbirth, infant death, premature delivery, low birth weight, chronic respiratory problems, blindness, and mental retardation or other manifestations of severe brain damage (Eng & Butler, 1997). Lastly, infection with one STI can increase the transmission of other STIs, including HIV.[ix]

Cancer Risks: HPV is associated with at least 80 percent of invasive cervical cancer cases, and women with HPV infection of the cervix are 10 times more likely to develop invasive cervical cancer than are women without such infection (Eng & Butler, 1997). Certain types of sexually acquired HPV are also now considered to be a cause of most cancers of the vagina, vulva, and anus. Although each of these cancers occurs less frequently than does cervical cancer, taken together they equal nearly half the number of cases of cervical cancer in the United States (Eng & Butler, 1997). Among the largest number of deaths related to STIs other than HIV are those due to cervical and other HPV-related cancers, and chronic liver disease, and liver cancer caused by hepatitis B.

Health Relevance & Costs

Sexually Transmitted Infections (STIs) remain a major public health challenge in the United States. While substantial progress has been made in preventing, diagnosing, and treating certain STIs in recent years, the Center for Communicable Disease currently estimates that 19 million new infections occur each year, almost half of them among young people. In addition to the physical and psychological consequences of STIs, these diseases also exact a tremendous economic toll to the American health system. Direct medical costs associated with STIs in the United States are estimated at $13 billion annually. The direct costs of treating STIs and their complications are estimated at $8.4 billion per year. These estimates do not include indirect, non-medical costs, such as lost wages and productivity

[2] Genital Human papillomavirus infection

due to STI-related illness, or the costs that ensue when STIs are transmitted to infants, which can result in significant life-long expenditures (KFF, 1998b).

CORRELATING SEXUALLY TRANSMITTED INFECTIONS & EXPOSURE TO VIOLENCE

The effects of violence on a victim's health are severe. In addition to the immediate injuries from the assault, women may suffer from many other conditions including chronic pain, gastrointestinal disorders, and eating problems. Exposure to violence is also associated with many mental health problems such as anxiety, post-traumatic stress disorder, and depression. Women who are abused not only suffer from an increased risk of sexually transmitted infections, including HIV/AIDS, but also increased risks of unplanned and early pregnancies. Research studies highlight correlations as follows:

- In a 1999 study, it was found that 40% of women with a history of physical, sexual and/or emotional abuse had been diagnosed with one or more sexually transmitted infections. In comparison, only 18% of non-abused women had been diagnosed with one or more STIs.[x]

- According to a U.S. study, women who experience intimate partner abuse are three times more likely to have gynecological problems than non-abused women.[xi]

- A three-year study of 500 African American females ages 14-18 found that adolescents with a history of dating violence were almost three (3) times more likely to have a sexually transmitted infection, three (3) times more likely to have non-monogamous male partners, and half as likely to use condoms than other adolescents.[xii]

- Survivors of abuse are more likely to practice high-risk sexual behaviors.[xiii]

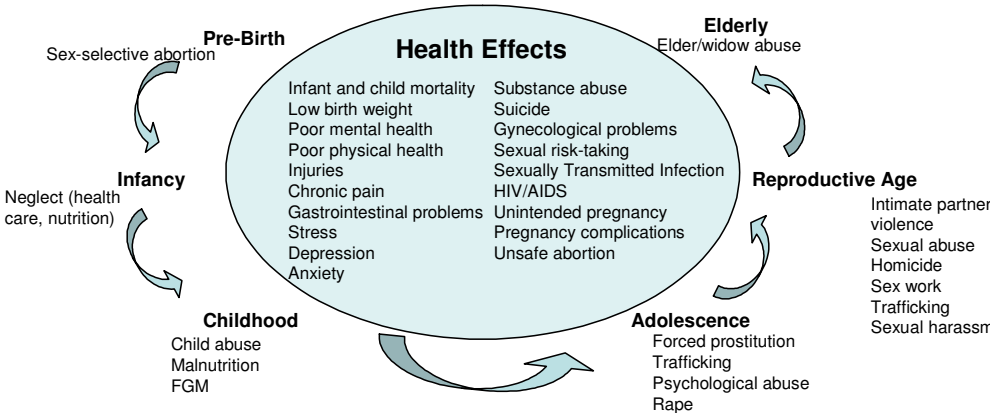
While violence against women is a serious violation impacting women's reproductive health, little attention has been paid to the serious health consequences and the health needs of abused women and girls. Women who have experienced physical, sexual, or psychological violence suffer with health problems, often in silence from health practitioners. They have poorer physical and mental health, suffer more injuries, and use more medical resources than non-abused women.[xiv]

- Women who disclose that they are infected with HIV also may be subjected to further violence.[xv]

Sexual abuse, especially forced sex, can cause physical and mental trauma. In addition to its resulting in sexually transmitted infections and HIV/AIDS, it can result in damage to the urethra, vagina, and anus.[xvi]

- Women who have been sexually abused are much more likely than non-abused women to use family planning secretly, to have their partner stop them from using family planning, and to have a partner refuse to use a condom to prevent disease.[xvii] See figure below:[xviii]

Life Cycle of Violence Against Women and Its Effects on Health



Innovation: Currently, when patients at risk are identified, they are offered appropriate counseling in risk reduction, cervical screening, screening for HIV and other sexually transmitted infections, and referral for drug treatment, when indicated. Yet, the ultimate goal to address the growing crisis of STIs among poor women is to inform and empower them, and refer them for social and psychological services as needed, so they can better protect themselves and their families.

Consequently, his collection of data has led collaborators from multiple disciplines of *New Methodologies* to plan the development of an intervention model that will pilot culturally-specific violence prevention training. Based on the Consortium's staffing capacity to provide services in eight different languages and its innovative approach to multi-generational program delivery, this model will integrate the dynamics of culture, age and gender.

RESEARCH PROGRAM

This data demonstrates the multifaceted dimensions of morbidity, mortality, and the costs that result from violence towards women. It further highlights the vital and central role of STI prevention and the need to combine it with violence prevention to improve the health among women and infants. Data from these and other diverse sources—HIV/AIDS and STI case reporting[xix]—point to an increasing burden of STI and high potential for further transmission among women; and, economically disadvantaged minority women are disproportionately affected.[xx]

To address these issues, Bay Area Consortium for Quality Health Care (Consortium), in collaboration with the University of California at Berkeley and San Francisco, Holy Names University, Children's Hospital Oakland, Providing Alternatives to Violence, and the California Board of Registered Nursing, will implement an innovative research initiative entitled, *New Methodologies in Treatment & Reduction of Sexually Transmitted Infections (New Methodologies)*. *New Methodologies* will address these prevalent health issues by investigating a possible correlation between: treating women for post violence stress disorders and reducing their exposure to continued violence; improving their STI treatment adherence; and reducing their rates of STI recurrence.

This research plan will also include the development of a violence prevention training program targeted at women exposed to violence who are consequently limited in their ability to protect themselves from unsafe sex situations. After two years of data collection, research findings will be utilized to develop and pilot a statewide, professional development curriculum to train health providers to address these specific gender/sex factors in STI treatment and treatment adherence.

RESEARCH IMPLEMENTATION

Researchers will test the hypothesis that treating women for stress conditions related to violence and training them in violence prevention will improve their STI treatment adherence and rates of STI recurrence. To implement the program, research partners will develop an Advisory Board that will consist of directors from each agency, a community member and representative of the target population. This Advisory Board will provide continuous project oversight over the two-year period in regards to data collection, evaluation, cultural competency, and program compliance.

Study Population

The research of *New Methodologies* will target the Consortium's exceptionally diverse client base of underserved, uninsured, and low-income women from four clinic sites. Researchers will study a multi-generational cohort while integrating factors of demographics, types of abuse, socio-economics and behavior into the research methodology. Women and girls will be targeted from three public health jurisdictions in Northern California as listed below:

City of Berkeley Public Health
- Berkeley Womens Health Center (40 clients)

City and County of San Francisco Public Health
- SF clinic name (80 clients)

Alameda County Public Health
- Market St. Clinic name (40 clients)
- Other clinic name (40 clients)

Identification & Data Collection

The Principal Investigator, Troy Duster, will develop the questionnaire design, data collection, analysis and interpretation methodology with his support team from the University of California Berkeley. Through his leadership, Bay Area Consortium for Quality Health Care will coordinate partners in the data collection process.

Women attending any one of the four clinics will be asked to complete a self-administered questionnaire that ascertains demographic, clinical, and behavioral information. Questions regarding recent and lifetime physical and verbal abuse will be included. Standard diagnostic tests and therapy for a variety of STIs will be administered when indicated, as a matter of routine care. Assessment for resultant Post Traumatic Stress Disorder (PTSD) will also be conducted.

200 questionnaires will be administered in year one. Four cohorts will be defined as adolescent (13-15), young women (16-21), seasoned women (22-50) and older women (51-85). Each cohort will contain a group consisting of women that have ever had a STI and were exposed to violence. A control group consisting of women that have ever had a STI and were not exposed to violence will also be surveyed. The research design will allow for analysis of other key demographic, social-economic and behavioral variables within each cohort and between control groups.

1. Data collection, analysis, and interpretation
    a. Females from adolescence through older ages will be screened for STI's
    b. Diagnosed females will receive appropriate clinical treatment for STI's
    c. All females will be asked to complete a one-on-one interview with a trained staff member to ascertain exposure to violence
    d. Women exposed to violence will be asked to submit a cortisol sample to identify and track the physiological evidence of stress. The test will be administered by staff that does not have information about each patient such as the degree of patient's exposure to violence or whether they are diagnosed with PTSD
    e. All females will be assessed for PTSD and any other stress-related disorders

Intervention & Treatment

Researchers will examine the impact of treatment on stress-related conditions caused by violent experiences, including Post Traumatic Stress Disorder (PTSD); and the impact of violence prevention training on treatment adherence and the recurrence rate of STIs.

1. Treatment – Sexually Transmitted Infections
   List procedure of treatment

2. Treatment – Stress-Related Conditions
   Researchers in a study[xxi] found that girls from urban, inner-city areas who were exposed to chronic and endemic violence developed full or partial post-traumatic stress disorder. Consequently, *New Methodologies* researchers will examine the impact of treatment on stress-related conditions caused by violent experiences, including Post Traumatic Stress Disorder (PTSD).

   Laboratory Methods: The presence of PTSD will be demonstrated by cortisol levels exceeding x – Insert laboratory testing methods.

   Patients diagnosed with specific stress-related or mental health conditions will be referred to counseling services and treated under medical care for a duration of 12 to 18 months.

3. Treatment – Recurrent Exposure to Violence
   Since women in violent relationships are less likely to take precautions during sex, clients will be provided with violence prevention training to increase their safety and potentially reduce risk factors leading to a recurrence of STIs.

ANALYSIS & RESEARCH SEQUENCE

GOAL1: **Determine the intervention effectiveness of post violence treatment and violence prevention training in reducing STI recurrence.**

GOAL 2: **Determine the impact of treatment for stress related disorders on STI treatment adherence and recurrence.**

Phase One

- Correlate rates of STI exposure with exposure to violence and symptoms of PTSD
- Correlate cortisol levels with exposure to violence and symptoms of PTSD
- Prevention of Recurrent Violence: Workshops organized by target population in each of the four clinics: Addresses violence prevention, communication skills, anger management, critical thinking, empowerment, goal setting, relationship skills, parenting.

Phase Two

- One year from initial intervention, telephone interviews with participants will be conducted to include and assess exposure to violence and recurrence of STIs.
- All participants will be invited to participate in a health assessment. At this time, current cortisol levels will be compared with the previous year. Home visits will be conducted as necessary. Results will be compared for all groups.

GOAL 3: **Identify emerging practices in health care delivery, which will lead to better identification and assistance of women with PTSD or other stress related disorders on STI treatment adherence.**

PTSD Identification: Oftentimes, in clinical practice, these women are not identified or treated for symptoms, constituting a potential, critical barrier to success in the field of STI prevention. Researchers will measure cortisol levels to diagnose and track stress responses.

GOAL 4: **Investigate cultural and situation-based antecedents of health disparities for women with STIs through review of risk factors for teen girls.**

GOAL 5: **Establish replicable guidelines for efficient health care delivery that more effectively prevents STI recurrence for low-income women.**

Statewide Leadership & Professional Development: Through collaboration with the California Board of Registered Nursing and Holy Names University, partners will build upon research findings to develop and pilot a statewide, professional development curriculum to train health providers to expertly address race, ethnicity, and gender/sex role factors in STI treatment and treatment adherence. Consequently, the successful implementation of the *New Methodologies* initiative will prospectively demonstrate statewide significance.

Partner Roles

The Principal Investigator and a partnering agency director will supervise each aspect of the *New Methodologies* project. As Principal Investigator, Troy Duster will have primary responsibility for achieving the success of the project, while also complying with the financial and administrative policies and associated regulations. He will direct the execution of the budget and justification in accordance with allowable cost principles. Executive Director Gwen Rowe Lee Sykes will administer and coordinate the project as lead applicant agency. Executive Director Lorie Hill will coordinate the Consortium's staff in the delivery of violence prevention training. She will work closely with Gwen Rowe Lee Sykes and other partners in the design of the program to develop culturally-specific curriculum dynamics which also target women who are exposed to violence and who are consequently limited in their ability to protect themselves from unsafe sexual situations. Add further detail of roles

ROLES OF COLLABORATING PARTNERS

INSTITUTIONS	PROJECT ROLE	PARTICIPATING DIRECTORS
Bay Area Consortium	Lead Applicant	▪ Gwen Rowe Lee Sykes, DrPH
Board of Registered Nurses	Inform the curriculum development process	▪ Insert
Children's Hospital Oakland	Insert	▪ Barbara Staggard
Holy Names University	Insert	▪ Edith Jenkins-Weinrub, EdD ▪ Carolyn D. Harris-Muchell, PhD
Kaiser Research	Insert	▪ Mark Alexander
Providing Alternatives to Violence	Violence Prevention Curriculum Development/ Treatment model development	▪ Lorie Hill, PhD
University of California Berkeley	Principal Investigator	▪ Troy Duster, PhD
University of California San Francisco	Insert	▪ Henry Geoffrey Watson, M.D. ▪ Carolyn D. Harris-Muchell, PhD

Measurements of Success

The goal of the this initiative is to reduce the recurrence of STIs for women while also reducing their risk factors for continued exposure to violence. Accordingly, the Consortium will implement the research program to achieve the outputs and short-term outcomes as listed below:

THE SHORT-TERM OUTCOMES THROUGH WHICH THE GOAL WILL BE PROMOTED ARE:

A. Increased identification of women exposed to violence and women at risk for continued violence
B. Increased identification of women with stress-related conditions due to exposure to violence
C. Increased knowledge of the intersection of exposure to violence, violence recurrence, and risk and protective factors, and prevention/intervention strategies, and improved behaviors
D. Increased use of culturally relevant services and supports for STI prevention and intervention

THESE WILL PROMOTE THE MEDIUM-TERM OUTCOME THAT:

E. Participants will report increased or maintained protective factors and/or reduced risk factors for continued exposure to violence and increased ability to maintain treatment adherence.

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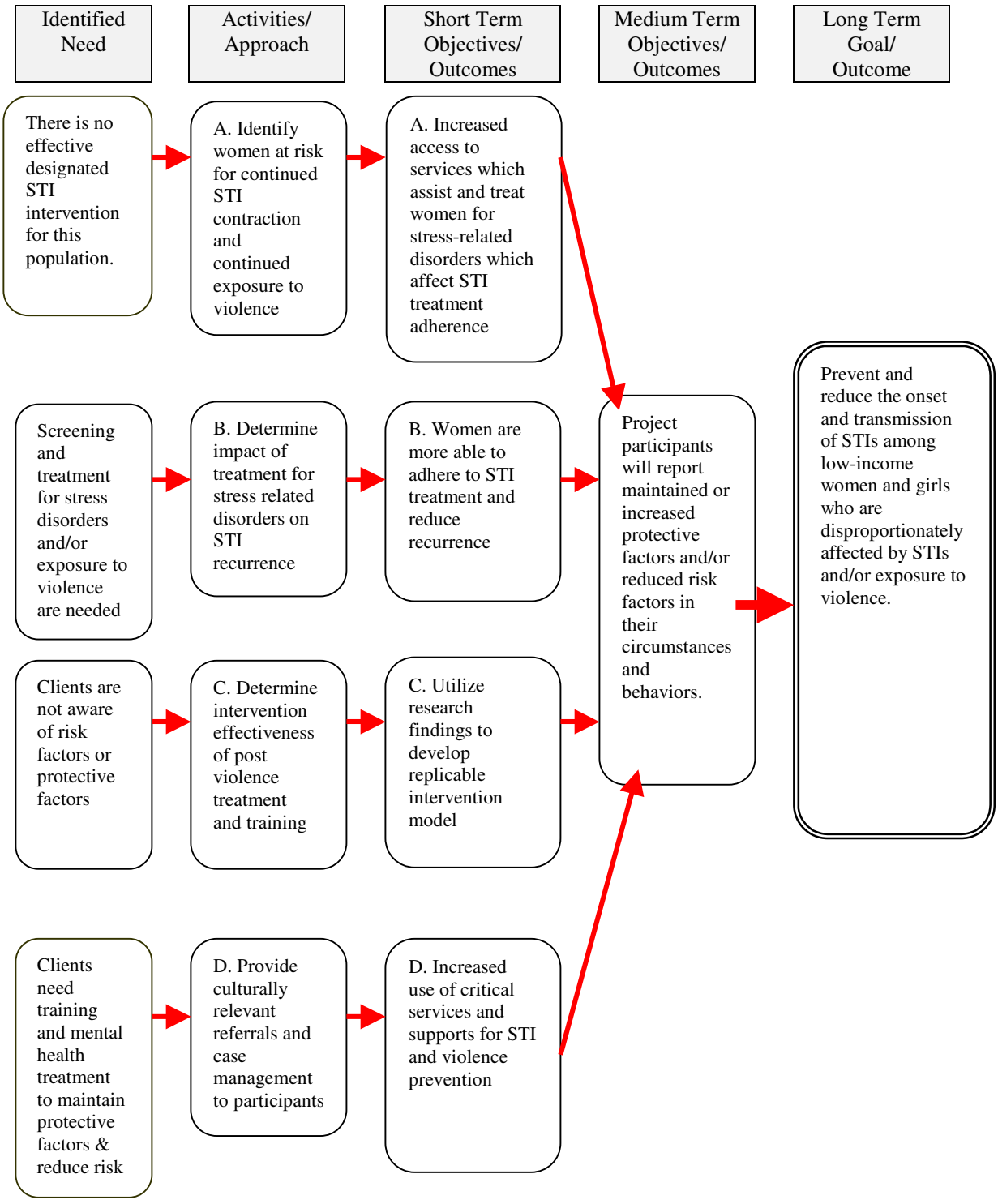
LOGIC MODEL – BAY AREA CONSORTIUM FOR QUALITY HEALTH CARE
NEW METHODOLOGIES IN TREATMENT & REDUCTION OF SEXUALLY TRANSMITTED INFECTIONS



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BAY AREA CONSORTIUM FOR QUALITY FOR HEALTH CARE

QUARTERLY TIMELINE – YEAR ONE

ACTIVITY	1st June '07	2nd Sept '07	3rd Dec '07	4th Mar '08	Year Two	PARTNER/AGENCY
Advisory Board meetings	X	X	X	X	X	All partners
Finalize and update planning	X					All partners
Establish project evaluation parameters	X					PI & Program Administrator
Finalize data collection procedures	X					PI & Program Administrator
Conduct client outreach	X					Consortium program staff
Start client identification and medical screening	X	X				Consortium medical staff
Finalize violence prevention curriculum	X					Lorie Hill (PAV)
Start stress-disorder treatment		X				
Start violence prevention training		X				Lorie Hill (PAV) & Consortium
Program Evaluation assessment Phase I			X			Advisory Board
Program Evaluation assessment Phase II				X		
Final analysis of data and determine research findings				X	X	Advisory Board
Program Evaluation completion				X	X	Advisory Board
Review curriculum development plan for statewide provider training					X	Advisory Board
Project End May 31, 2008					X	
Data collection - Calling clients					X	Consortium staff
Year two activity					X	

Please add further detail

Peer Inclusion

Involving Representatives of the Target Population in Project Planning: The Consortium encourages its community-based partners to include and involve members of the target population in planning, implementing and evaluating the effectiveness of the proposed project. Additionally, it is its mission to work in partnership with the community to ensure the optimal health of all people by recognizing that residents are more than consumers of public health services. Therefore, the Consortium actively involves residents in the planning, evaluation and implementation of health activities in their communities. The inclusion of peers who are at-risk for STIs will be especially important to overcome social and practical barriers. During meetings with peer representatives, key staff and partners will seek feedback on the effectiveness of existing and proposed program implementation, educational approaches and materials and quality of care issues.

Culturally Appropriate Policies, Programs and Practices

Due to the immense diversity of the San Francisco & East Bay Area population, the Consortium requires that its collaborating agencies maintain policies in cultural competency and participate in ongoing training. The Consortium's definition of cultural competence includes multiple language proficiency as well as an understanding that culture is defined not only by race and ethnicity, but also by sexual orientation, gender, class, age, neighborhood and other factors specific to the target population. The Consortium regards cultural competence as critical to a strengths-based and peer-focused approach to service delivery. Consequently, during the implementation process, the Advisory Board will create a Cultural Competence Subcommittee to develop and monitor cultural and gender competency for the program implementation. This will include cultural competence standards and performance indicators (system standards, clinical practice, and provider competencies) to ensure effectiveness system-wide.

Disability: Clients with disabilities can also be served through the *New Methodologies* initiative. Through disability access at multiple facilities and support resources, the program will comply with the American Disabilities Act to make provisions for disabled clients.

RESEARCH & HUMAN SUBJECTS

Bay Area Consortium for Quality Health Care is a culturally competent health provider, with a highly diverse staff at every level of service, including medical staff, board members, administrators and research assistants. In addition to the mission of the Consortium and the culture created in each of its clinic sites, it supports the highest levels of awareness and sensitivity to the diversity of the community members in the San Francisco Bay Area.

The Consortium and its project partners are committed to the highest level of privacy protection for all participants in this project. It's HIPPAA compliant in all of its data collection and storing procedures.

The following describes the steps the research team will take to ensure such protections:

Before data collection commences, approval to implement the research activities will be obtained through the Consortium's Institutional Review Board (IRB). Throughout the duration of the project, all individuals involved in obtaining consent or data collection will continue to work with and abide by the guidelines set by the IRB to protect the rights and confidentiality of all individuals who participate in the research project and follow-up data collection.

1. Protection of Clients and Staff from Potential Risks

The risks posed to individuals who participate in the planning, development, and implementation of the program and/or those who participate in the intervention program are minimal. The primary risks include:

1) A loss of confidentiality among individuals who participate in the research project and follow-up data collection and STI, HIV and HEP testing;
2) Disclosure of illegal activities/reportable offense to intervention staff, and
3) Discomfort from discussing situation and/or behaviors.

The Institutional Review Board at the Consortium has strict guidelines to minimize the possibility of these risks occurring, and how to handle them appropriately if they do arise. The following describes the procedures that the applicants will follow to minimize risks to participants and procedures that will be followed if they occur.

Research project, Evaluation, Data Collection and STI, HIV and HEP testing: In order to minimize the risk of violating the confidentiality of participants who agree to participate in the project, research assistants will assign them a 'client number' which, along with participants' initials, will be used from that point forward on all documentation associated with that client. A master list linking names and numbers will be kept by the research assistants under lock and key; and the Consortium will keep a duplicate copy. Personal names or contact information will never be allowed on data collection instruments. Consent forms and data collection instruments will be kept under lock and key in separate file cabinets. Only individuals involved in this study at the community based organization and the Consortium will have keys to the file cabinets. Regarding confidentiality issues related to STI, HIV and HEP testing, consent forms obtained by staff are HIPPA compliant and locked in a file cabinet. Only staff associated with the testing procedures has access to this cabinet.

Disclosure of Mandated Reporting Activities to Staff: Given that this grant addresses the issue of violence, participants may disclose information on activities that are mandated by law to be reported. Participants will be told that what they say will be kept confidential to the full extent that the law permits. The IRB at the Consortium has clear guidelines on what the mandated reporting activities are, and what to do in the case of disclosure of a reportable activity. If a participant reports physical or sexual abuse or neglect of a minor, staff is required by law to report this to the appropriate authorities. Other reportable offenses include disclosure of intent to commit suicide and/or intent to harm or kill another person. These offenses are directly reported to local law enforcement officials. It is the policy of the IRB at the Consortium to inform individuals in the Informed Consent forms and verbally as to what exactly is reportable, and that if an individual discloses any of them to staff, she/he is required to report them to appropriate authorities.

Discomfort from Discussing Situation and/or Behaviors: It is important for project staff to be a resource for participants who are involved in situations that may not be positive or healthy. Thus, in the event that participants discuss distressing situations, staff will have a list of resources in the community that participants can be referred to for any number of programs or services that they might need, such as legal aid, mental health counseling, assistance in finding a job, childcare, addiction treatment, and transportation.

2. Fair Selection of Participants

The target population for the proposed project is minority and low-income adolescent and adult females who are deemed to be at risk for STI, HIV and HEP transmission due to exposure to violence. The three public health jurisdictions are Alameda County including Oakland, San Francisco County and Berkeley Public Health Department serving the City of Berkeley.

The Consortium has four programs serving the health, social and educational needs of women and girls. The first three programs are clinic-based serving women and girls in three locations in low-income and racially diverse areas, with two clinics in Oakland and one in Berkeley. The fourth program is school based serving girls in three public and alternative school settings, including a juvenile detention center operated by Alameda County serving adolescent females in incarcerated settings. This includes females in the primary juvenile detention center as well as females who are living at a group home as they transition from the detention center back to the community.

The project will not specifically target other vulnerable populations such as pregnant women, children under 14 years of age or people with mental disabilities, though it is conceivable that some of the women targeted for this project may be pregnant.

Clinic staff located at each of the above locations will recruit participants for the project. The Consortium and its partners reach over 3,000 women a year; this project is estimated to reach approximately 500 to 600 adolescent and adult females each year.

3. Absence of Coercion

Participation in the research study project is completely voluntary. The project will consist of several components, including an intake assessment; referrals; STI, HIV and HEP testing; and Jump Start, Providing Alternatives to Violence (PAV)'s empowerment, communication and leadership skills, anger management and violence prevention program. Intake workers will explain to participants during the initial components of the project that they may opt out of any part of the project that feels uncomfortable or is unfeasible for them, and that they may withdraw from the project at any time.

Participants will not be compensated by grant project funds. Instead, the project work group will defer to project partners as to the most appropriate strategy for encouraging participation.

4. Data Collection

Data will be collected from adolescent and adult females women who have STI's, HIV and/or HEP. Health staff employed by the provider agencies at the clinic locations will collect all participant data. Health staff will also collect STI, HIV and HEP testing results. The results of these tests will go into the participants' randomly numbered file. The Consortium will not retrieve individual test results from the health department, but from the agency's participant files.

The specimens collected to conduct STI, HIV and HEP tests are sent to the contracting labs and discarded. These samples will not be used or stored by project staff or the evaluators.

A culturally appropriate, tested and validated survey will be used to collect data from females who qualify to participate in the project.

5. Privacy and Confidentiality
The process for collecting data and ensuring the privacy and confidentiality of participants is described above. Intake, test result and survey data will be collected by health workers and research assistants. Intake and survey data will be collected via interviews with participants, while test data (the results of tests) is noted on County Public Health Department forms, which are sent to the department; a copy of the form will stay in the participants' file at the peer workers' agency. All hard copy data will be kept in participants' files at each clinic site. However, approximately twice a year, the Consortium will ask for copies of the files in order to update records.

The identities of the respondents will be kept confidential. Health workers will assign each consenting participant a number, after which all surveys and forms associated with that individual will be designated with their client number. The master list will be kept by the community provider working with the participant as well as by the Consortium. These lists will be kept separate from all surveys and forms and in a locked file at both locations. At the community agency, only the research assistants have access to the files.

In addition to the protection of privacy and confidentiality discussed in Section 1, confidentiality of alcohol and drug abuse client records according to the provisions of Title 42 of the Code of Federal Regulations, Part 2 will also be maintained.

6. Adequate Consent Procedures
The Consortium will coordinate with community agency staff to obtain written informed consent from participants to be included in the research project at each site. If some project participants' home language is not English, translation will be provided.

The Consortium will recommend that health workers review the consent forms verbally with their clients to ensure comprehension and to answer any questions from participants. Finally, participants will be asked if they want a copy of the consent form they signed; if so, agency staff will make them a copy.

Because they contain the participant's full name, signed consent forms will not be kept in their general participant file, but will be stored elsewhere on the premises with the master list linking names to numbers. See sample consent forms in Appendix 3.

7. Risk/Benefit Discussion
The risks involved in participating in the research project and the evaluation are minimal. The research and health staff that will manage data collection are experienced with confidential collection procedures. Trained health staff will facilitate Jump Start, the empowerment and violence prevention groups. Problems during the course of the study are not anticipated. The benefits of collecting data from adolescent and adult females who have STI's and have experienced violence will fill in a number of gaps in information about how best to serve and address the needs of this population. This information is important to help prevent violence, to lower rates of reoccurrences of STI's and to strengthen the social skills and self-protection abilities of this population.

Protection of Human Subjects Regulations
Once the grant has been awarded, the evaluation staff will complete the application for IRB approval and submit it and all other required documents for review by the Consortium IRB before enrolling any clients in the proposed project.

EVALUATION PLANNING

See insert

PRELIMINARY STUDIES

ABOUT THE PRINCIPAL INVESTIGATOR

Troy Duster is Professor of Sociology at New York University, and he also holds the title of Chancellor's Professor at the University of California, Berkeley. He is the former Director of the American Cultures Center, and founding Director of the Institute for the Study of Social Change, both at the University of California, Berkeley. He has been a Visiting Professor or Visiting Scholar at Stockholm University, the University of British Columbia, the London School of Economics, Williams College, the University of Melbourne, and Columbia University. His books and monographs include *The Legislation of Morality* (1970), *Aims and Control of the Universities* (1974), *Cultural Perspectives on Biological Knowledge* (co-edited with Karen Garret, 1984), *Backdoor to Eugenics* (2003, 2nd Edition), and (co-author of) *Whitewashing Race: The Myth of a Colorblind Society* (2003). He is also the author of numerous articles on theory and methods published in the *American Sociologist*, *Temps Moderne*, and *Politics and the Life Sciences*.

Dr. Duster has been a member of the Assembly of Behavioral and Social Sciences of the National Academy of Sciences; the Committee on Social and Ethical Impacts of Advances in Biomedicine, Institute of Medicine; the Special Commission of the Association of American Law Schools; the Commission on Meeting the Challenges of Diversity in an Academic Democracy; and the Science Advisory Panel, National Institutes of Health, Research, on Violence. He is currently a member of the Board of Directors of the Social Science Research Council (2004), and President-elect of the American Sociological Association (2004).

He is the recipient of a number of research fellowships including awards from the Swedish Government, a Guggenheim fellowship, and a Senior Research Award from the Ford Foundation. He has been a member of the National Advisory Council for Human Genome Research (1996-1999), the Board of Directors of the Association of American Colleges and Universities (1997-2003) of which he served as Chair (2002-2003), and was also a member and then Chair of the National Advisory Committee on Ethical, Legal and Social Issues in the Human Genome Project (The ELSI Working Group). Along with Jerome Karabel, Dr. Duster co-directed a multi-year grant from the Ford Foundation on the effects of the end of affirmative action on the University of California.

A recent *Scientific American* profile of Troy Duster told of a 1997 meeting at the National Human Genome Research Institute where Duster made a historic contribution to the discourse. Years before the Human Genome Project had begun, Duster had already been patiently explaining that while genetic research cannot find race as a biological reality, race remains very much a *social* reality—with important biological outcomes, such as sharply higher rates of hypertension and prostate cancer in racialized populations. When the revolution in molecular biology arrived, Duster warned that DNA markers linked to ancestral origins would be used to attempt genetic explanations of these conditions—a dangerous pathway to the reinscription of the biology of race. "In large part, thanks to Duster," the *Scientific American* article said, "Collins and other geneticists have begun grappling with forensic, epidemiological and pharmacogenomic data that raise the question of race at the DNA level."

Distinguished Scholarship

Duster's research and writing have ranged widely across the sociology of law, science, deviance, inequality, race, and education. In addition to numerous book chapters, he has published in an extraordinary array of scholarly journals including *Nature, Social Problems, Science, Ethnicities, Representations, the Bulletin de Methodologie Sociologique, The American Sociologist, Philosophy and Social Action, Politics and the Life Sciences, Crime and Delinquency, Society, Social Psychiatry, The Black Scholar, Les Temps Modernes,* and *The Japanese Journal of Science*. His research has been translated into French, German, Italian and Japanese.

His first book, *The Legislation of Morality: Drugs, Crime, and Law* (1970), a classic in the drug field, showed that when the demographics of opiate addiction shifted, so did its definition and the law. When addicts were predominantly white, middle-class, middle-aged women, addiction was a health problem dealt with privately by

physicians. But when addiction spread among more "disreputable" groups like poor young men, it was redefined as a crime problem dealt with publicly by imprisonment.

Duster's other books include the seminal *Backdoor to Eugenics* (1990), which *The Nation* called a "lucid landmark." In his introduction to the second edition (2003), Pierre Bourdieu applauds Duster for showing the dangerous slide toward a "covert eugenics" that has emerged as "old mythologies" about intelligence and crime are "dressed in the biological sciences."

Duster has been an editor for *Theory and Society, Sociological Inquiry, Contemporary Sociology, The American Sociologist*, and the ASA's Rose Monograph Series. He is currently a member of the Social Science Research Council, and has served on committees for the National Academy of Sciences, the American Association for the Advancement of Science, the American Association of Law Schools, the National Science Foundation, the Russell Sage Foundation, the National Institutes of Health, and he was Chair of the Ethical, Legal and Social Issues Committee of the Human Genome Project.

Among other awards, Duster has received a Guggenheim Fellowship at the London School of Economics, an honorary Doctor of Letters from Williams College, and the DuBois-Johnson-Frazier Award from the American Sociological Association. He's currently Professor of Sociology and Director of the Institute for the History of the Production of Knowledge at New York University, as well as Chancellor's Professor of Sociology at the University of California, Berkeley, where he has taught since 1970.

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