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## A Comparison of Consumer-Controlled and Traditional HIV Counseling and Testing: Implications for Screening and Outreach among Injection Drug Users

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A COMPARISON OF CONSUMER-CONTROLLED AND TRADITIONAL HIV COUNSELING  
AND TESTING: IMPLICATIONS FOR SCREENING AND OUTREACH AMONG INJECTION  
DRUG USERS

by

BRADFORD N. BARTHLOW

Under the Direction of Roger Bakeman

ABSTRACT

Recent advances in HIV antiretroviral therapy and the availability of prophylaxis for opportunistic infections, combined with the opportunity to prevent perinatal HIV infection, underscores the value of early diagnosis of HIV infection. HIV antibody home test kits offer individuals the opportunity to collect a blood sample, send it anonymously to a laboratory, and receive counseling and referral over the phone. Home HIV testing may reduce barriers to testing that have precluded individuals from learning their HIV serostatus, and if seropositive, from taking advantage of efficacious therapeutic and preventive regimens.

This study employed a randomized-controlled prospective field trial design to determine if the availability of home testing increased HIV testing relative to traditional counseling and testing among injecting drug users in three HIV prevention/drug treatment contexts; methadone maintenance, hospital-based detoxification, and syringe exchange. Theoretical correlates to HIV testing were also evaluated. Multivariate analyses demonstrated that participants randomized to home testing were 2.2 times more likely than those randomized to traditional counseling and testing to test for HIV antibodies in this study after controlling for demographic, HIV risk, and theoretical variables. No differences were observed between testing methods with regard to obtaining HIV test results. The relationship between HIV testing and test type was

moderated by drug treatment context and history of homeless, with home testing resulting in increased testing among methadone participants and persons without a history of homelessness. Analyses of theoretical variables suggested that prevention education stressing the benefits of HIV testing, personal risk of HIV infection, and efficacy of available treatments could increase HIV testing among injecting drug users. Participants randomized to home testing were more satisfied with testing and telephone-based counseling than were those receiving traditional testing and face-to-face counseling.

Home testing was associated with increased testing perhaps due to reduced barriers to testing. To further reduce barriers to testing and to increase testing among injecting drug users, consideration should be given to incorporating oral fluid testing and rapid result capability in home test kits. Counseling could be made available as needed, delivered by telephone, and contingent upon the volitional control of the testing consumer.

INDEX WORDS: Human Immunodeficiency Virus, Injecting drug users, HIV testing, Home testing

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AMONG INJECTION DRUG USERS

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A Dissertation Submitted in Partial Fulfillment of Requirements for the Degree of

Doctor of Philosophy

Georgia State University

2005

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2005

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## LIST OF ABBREVIATIONS

AIDS	Acquired Immunodeficiency Syndrome
CDC	Centers for Disease Control and Prevention
CODAAP	Coordinating Office of Drug and Alcohol Abuse Programs
CT	HIV counseling and testing
CCT	Consumer-controlled testing
HIV	Human Immunodeficiency Virus
IDU	Injection drug user/Injection Drug Use
NPHS	North Philadelphia Health Systems
PPP	Prevention Point Philadelphia
RAB	Risk Assessment Battery
STD	Sexually transmitted disease
STI	Sexually transmitted infection
TCT	Traditional counseling and testing
TPB	Theory of Planned Behavior
TRA	Theory of Reasoned Action

## CHAPTER 1

### HISTORICAL PERSPECTIVE

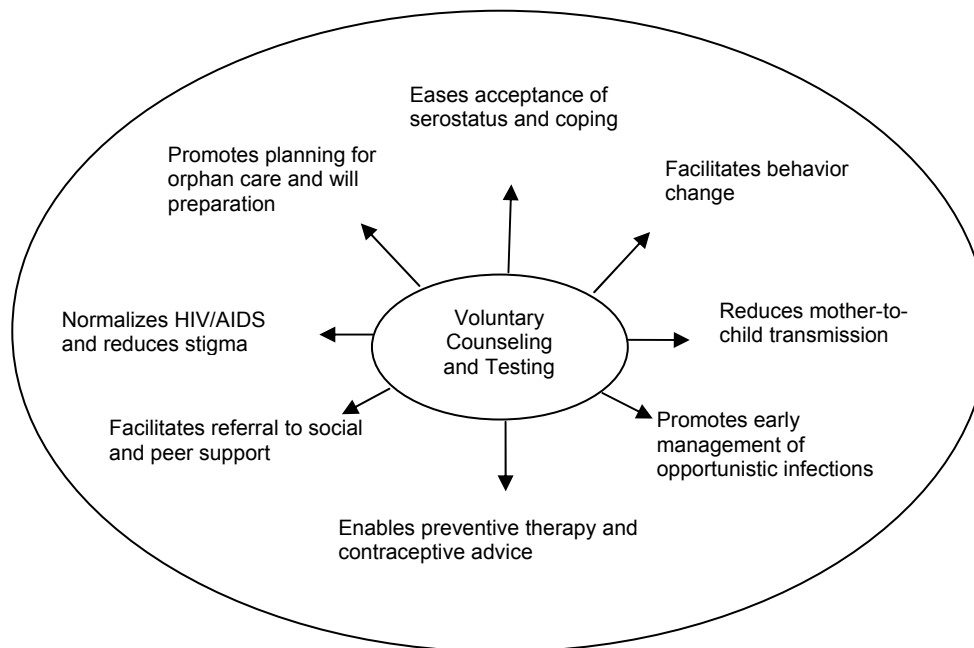
In 1985, HIV antibody testing first became available in publicly funded “alternate test sites” to allow persons to determine their infection status without having to donate blood, thus, the original intent of testing was to protect the blood supply (Peterman, Todd, & Mupanduki, 1996). In 1987, however, an interest in helping uninfected individuals reduce their HIV risk, and in assisting HIV seropositive individuals from infecting others prompted the Centers for Disease Control and Prevention (CDC) to rename these testing sites to “HIV counseling and testing (CT) sites” (Peterman et al., 1996). The secondary prevention implications of early HIV diagnosis became more salient after the beneficial effects of treating asymptomatic HIV seropositive patients with AZT were reported in 1990. Since then, HIV CT has become the cornerstone of primary and secondary prevention efforts in the United States (Cates, Jr. & Handsfield, 1988; Higgins et al., 1991; Peterman et al., 1996; Phillips, Flatt, Morrison, & Coates, 1995), with the CDC increasing expenditures from 9.8 to 116.2 million dollars between 1985 and 1994.

Evidence as to the effects of CT on reducing HIV risk behavior has been mixed (Higgins et al., 1991). Sampling biases, cohort effects, lack of adequate contrast groups, and measurement error, have all contributed to ambiguous results reported in the literature (Cates, Jr. et al., 1988). Among 11 early studies of CT targeting injection drug users (IDUs) reviewed by Higgins et al., several found no effect related to CT, some improved needle hygiene behavior for all groups regardless of CT, one reported increased HIV risk behavior among those receiving CT, and another detected a reduction in HIV risk after CT which was not sustained at follow-up

(Higgins et al., 1991). These authors concluded that behavioral change in these studies could not be attributed to learning ones' HIV status.

More recent studies have reported beneficial public health outcomes associated with CT. Women enrolled in a prospective study recruited from four Connecticut community health clinics were more likely to initiate safer sex behavior if they had received CT (Higgins et al., 1991; Morrill, Ickovics, Golubchikov, Beren, & Rodin, 1996). Knowledge of one's positive HIV serostatus has been associated with admission to drug treatment programs (McCusker et al., 1994), and among IDUs enrolled in a study in Bangkok, CT was associated with increased use of condoms and contraception with primary sex partners (Vanichseni et al., 1992). In methadone maintenance programs, CT has been associated with less persistent illicit drug use (Farley, Cartter, Wassell, & Hadler, 1992), and in a randomized-controlled trial of out-of-treatment IDUs and crack users, CT was found to be associated with a reduction in both the number of sex partners and the exchange of sex for money or drugs (Haiou, Stark, Weir, & Gould, 1996).

Opportunities for secondary prevention and the prevention of perinatal HIV infection further underscore the value of early diagnosis of HIV infection. Increasingly efficacious early antiretroviral therapy (Ho, 1995) and antibiotic prophylaxis for opportunistic infections (Kaplan, Masur, & Holmes, 2002), can now improve the health status of HIV-infected persons receiving such therapies. Furthermore, knowledge of positive HIV serostatus among pregnant women now offers the opportunity to reduce perinatal infection by offer prophylaxis during labor and delivery (Peckham & Gibb, 1995). Thus, in addition to the important primary prevention goals of behavioral risk reduction, the increasing efficacy of secondary prevention strategies further reinforces the potential public health value of an early HIV diagnosis. HIV CT has been conceptualized by the World Health Organization's UNAIDS program (Joint United Nations Programme on HIV/AIDS, 2002) as an entry point for HIV prevention and care (Figure 1).



*Figure 1.* Counseling and testing as an entry point for HIV prevention and care

#### MISSED OPPORTUNITIES OF TRADITIONAL COUNSELING & TESTING

There is evidence, however, that many persons at-risk of infection have not been tested (Anderson, Hardy, Cahill, & Aral, 1992). For example, among clients participating in the New Haven Needle Exchange Program between 1990 and 1992, less than half had previously been tested, although 68% had recently seen a health care provider (Rebchook, Guilfoile, & Lenaway, 1996). Similarly, a Colorado needle exchange program reported that only 55% of their clients had previously been tested for HIV antibodies (Rebchook et al., 1996). Among patients enrolled in a study evaluating missed opportunities for CT in a high HIV prevalence South Bronx community, 51% had not previously received CT (Weber et al., 1996).

Of at-risk individuals who do seek testing, many are motivated to do so because of physical symptoms related to HIV disease (Wortley et al., 1995). This dynamic has been observed among IDUs who upon becoming ill, were tested for HIV antibodies primarily in

hospital settings (Wortley et al., 1995). The CDC reports that 51% of drug using individuals first test positive for HIV within one year of receiving an AIDS diagnosis, and approximately a third of persons first testing positive do so within 2 months of an AIDS diagnosis (Wortley et al., 1995).

A variety of barriers to HIV testing have been cited in the literature, including denial of HIV risk, lack of awareness of the availability of testing services, concerns regarding confidentiality, the possibility of discrimination and loss of health insurance, fear of positive results, and a perception that there is no benefit from knowing ones' status (Myers, Orr, Locker, & Jackson, 1993; Lyter, Valdiserri, Kingsley, Amoroso, & Rinaldo, Jr., 1987). When asked if they might go to a neighborhood health center for HIV testing, participants in a CDC-sponsored qualitative study often provided confidentiality-related examples for avoiding HIV testing such as (Centers for Disease Control and Prevention, 1996):

“Nobody wants to go down there. People don't want you to see them walking in and out of there.”

“...well, me myself I don't think that I would like going to a neighborhood health center because you're going to where you live at, you are going to see some of the same people you live with...”

“... I would go out of state, out of town, you know, until it had to be a final or a recent thing where I would – couldn't travel, probably get sick because I may be sick, you know, and then I would probably make it a local...”

In addition to these barriers, those who do get tested for HIV antibodies often don't return for their test results. Reports on CT in publicly funded US sites indicate that of the 4.9 million tests performed in 1993 and 1994, only 58% of individuals returned for post-test counseling (U.S.Department of Health and Human Services, 1996). Similarly, 1996 data show



differences in return rates for HIV test results by site, ranging from 44% in private medical clinics to 82% in HIV CT specific sites. The proportion of individuals testing at drug treatment centers who returned for their test results during this time was 69%. Return for HIV test results also varied widely by race with 52% of Blacks returning for results compared to over 75% for Whites and Asians. A low return rate for African-Americans is of concern given their overrepresentation among HIV infected individuals.

These factors suggest that improvements could be made in the CT system, such that persons engaging in high-risk behavior would have a greater likelihood of getting tested and learning their test results. Such improvements would enhance the opportunity for individuals to make informed decisions based on the knowledge of their antibody status, to change behaviors that put themselves and others at risk of infection, and to obtain early medical care if HIV infected (Phillips & Coates, 1995). These realizations along with the recent Food and Drug Administration (FDA) approval of a rapid HIV test in the United States, has resulted in the CDC initiating new strategies for HIV prevention targeting HIV infected persons that include reducing barriers to HIV testing, increasing testing and early diagnosis among persons at-risk of HIV infection, and providing treatment for HIV infected persons (CDC, 2003).

#### THEORETICAL CORRELATES OF HIV TESTING

An evaluation of alternative HIV counseling and testing strategies should be theoretically grounded in order to facilitate the development and testing of hypotheses related to testing. Furthermore, the application of theory may suggest program refinements that could increase the likelihood of at-risk individuals getting testing for HIV antibodies, learning their antibody status, and if appropriate, commencing therapeutic regimens in a timely and optimal manner. Finally, available theories may facilitate the interpretation of data and suggest areas for future research.

Many theories have been employed to facilitate the understanding of HIV risk behavior and to guide the development of HIV-related primary and secondary prevention programs, including the Health Belief Model (Hochbaum, 1958; Rosenstock, 1974), the Theories of Reasoned Action (Ajzen & Fishbein, 1980; Fishbein & Ajzen, 1975) and Planned Behavior (Ajzen, 1985), the Transtheoretical Model of Health Behavior Change (Prochaska & Velicer, 1997), and Empowerment Theory (Rappaport, 1981; Rappaport, 1984). For this study, Empowerment theory and the general principles of community psychology (Florin & Wandersman, 1990) provided process-related direction (e.g., for developing collaborative partnerships with target community and key stakeholders), the Transtheoretical Model offered an organizing schema to frame and guide statistical analyses, the Health Belief Model and the Theories of Reasoned Action and Planned Behavior proffered individual-level constructs potentially useful for understanding HIV testing behavior and for informing the development of improved HIV testing services.

### *Empowerment Theory*

Empowerment has been described as the process by which heretofore silent, isolated, or marginalized people are provided opportunities to control their own destiny and influence decisions that affect their lives (Rappaport, 1981). Empowerment suggests a distinct approach of developing interventions and creating social change (Zimmerman, 2000) and directs attention toward health, adaptation, competence, and natural helping systems. An empowerment perspective assumes that many social problems exist due to unequal distribution of and access to resources. Empowerment theory includes both a focus on process and on outcome and is context and population specific, thus, it takes different forms for different people in different contexts (Zimmerman, 2000).

The empowerment perspective is consistent with the theme of consumer-controlled HIV testing. That is, CCT provides an opportunity for individuals to initiate testing on their own and to learn their results if they choose. Further, the notion of CCT embraces the competence of individuals to be able to follow the instructions included with a self-testing kit, obtain an adequate biologic sample for testing, have the psychological resilience to cope with a HIV seropositive test result, and choose to seek counseling if they feel the need. CCT also is consistent with empowerment in that it offers new behavioral choices to people who may lack an intention to change their behavior.

Early objections to consumer-controlled HIV testing were perhaps inconsistent with the values of empowerment and community psychology. Initially, there was unanimous opposition to CCT by the CDC, the American Medical Association, and the Gay Community (Phillips et al., 1995). Many concerns regarding the technology and implications for home testing were expressed about the specificity and sensitivity of a test using consumer-collected specimens, the provision of adequate and ethical pre- and post-test counseling, the possibility of adverse psychological impact for individuals testing positive, confidentiality concerns, and fears of test abuse (Phillips et al., 1995). Similar concerns had also previously been expressed about home pregnancy testing for women and even clinic-based HIV testing. There has now been a shift in attitude with regard to home testing and CDC has withdrawn its opposition and has issued a statement in support of CCT. However the FDA has not approved HIV test kits for home-use which would allow consumers to purchase a test kit, collect a sample in private, and determine their own HIV test results within minutes. The Federal Trade Commission has also warned that some home-use HIV test kits, many of which are available on the Internet and in the "gray" market (i.e., unauthorized imports), supply inaccurate results (Federal Trade Commission, 2001).

An empowerment orientation also suggests that community members should have an active role in establishing the agenda for, and the implementation of, community projects and research studies (Zimmerman, 2000). This study was guided using an empowerment framework. Community forums were conducted to educate and garner input from community members. A community advisory board comprised of members of the substance using target populations provided useful guidance for protocol development and implementation. Finally, planning sessions with key stakeholders including government officials, university partners, program managers, industry partners, and consumers of needle exchange, detoxification, and methadone maintenance services helped ensure community participation, endorsement, and study integrity.

#### *Transtheoretical Model*

Prochaska's transtheoretical model was developed in the context of psychotherapy for substance users and asserts that lasting behavior change is preceded by a process of incremental movement through cognitive and behavioral stages (Prochaska et al., 1994). The transtheoretical model defines six stages through which a person moves before consistently adopting new behaviors; *precontemplation*, *contemplation*, *preparation*, *action*, *maintenance*, and *termination* (Prochaska et al., 1997).

*Precontemplators* have not yet begun to perceive a behavior as a problem and are not consciously evaluating their behavior(s) with a view toward change (Montoya, 1997).

*Contemplators* have begun a process of "decisional balance," evaluating the "pros" and "cons" involved with making a behavior change. For individuals in the *preparation* stage, the pros begin to outweigh the cons, however, these individuals continue to evaluate the implications of behavior change and have not yet decided to enact change. Because individuals in the preparation stage may experiment with a behavior, increasing self-efficacy is considered as

important as decisional balance for moving to the action stage. In the *action stage* doubts about the benefits of a behavior change have generally been resolved and the new behavior is implemented on a consistent basis. The *maintenance* stage is characterized by a mastery of the skills required to consistently perform a behavior, and at this stage an individual's behavior is considered to have changed.

Stage models have been considered useful for suggesting important "markers" in the change process (Catania, Kegeles, & Coates, 1990b). In both applied and intervention studies, stage-matched interventions have been associated with greater intervention efficacy and study retention (Prochaska et al., 1997), as well as increased treatment utilization (Ockene & Ockene, 1988). Furthermore, it has been suggested that the failure of interventions to demonstrate greater efficacy may be because only a small percentage of persons are in the action stage at a given point in time and these individuals are those most likely to change (Prochaska, DiClemente, & Norcross, 1992). Individuals in the stages preceding action may benefit from interventions; however, the benefit is likely to be movement from one stage to the next rather than actual behavior change. In this study, the transtheoretical model will be used to stage participants regarding HIV testing. The analysis will take stage into account when evaluating the primary outcome variables. The hypothesis related to stage will be that study participants in the action and maintenance stages will be more likely to test for HIV antibodies and return for their test results than participants in the precontemplation, contemplation, and ready for action stages.

### *The Health Belief Model*

The Health Belief Model (Hochbaum, 1958) may be one of the most widely used theories of health protective behavior (Weinstein, 1993; Dorr, Krueckeberg, Strathman, & Wood, 1999) and has been applied in studies of HIV risk behavior among MSM, minorities, and

women. The Health Belief Model assumes that an individual's health behavior is related to perceived susceptibility to infection, perceived severity of consequences, perceived efficaciousness of protective action, and perceived barriers to protective behavior. In the context of HIV testing, the Health Belief Model suggests that individuals who perceive that they are susceptible to HIV infection, HIV disease is severe, it is beneficial to know one's HIV status, and that there are few barriers to HIV testing would be more likely than individuals who do not, to test for HIV antibodies and learn their HIV status (Dorr et al., 1999).

Perceived susceptibility has received the most attention from researchers examining the relationship between Health Belief Model variables and HIV testing (Dorr et al., 1999). Results have been mixed depending upon population surveyed. Surveys of the general population (Anderson et al., 1992), gay men (Myers et al., 1993), individuals waiting for mass transit (Kalichman & Hunter, ), and gay, lesbian, bisexual youth (Maguen, Armistead, & Kalichman, 2000), have found that individuals who perceive themselves to be at-risk of contracting HIV are more likely to have been tested in the past. Other studies have not found a relationship between HIV testing and HIV risk perception (Lyter et al., 1987; McCusker et al., 1988; Catania, Kegeles, & Coates, 1990a).

Perceived severity has had more limited evaluation with regard to HIV testing (McCusker et al., 1988). Contrary to predictions derived from the Health Belief Model, these authors found that men who chose to learn their HIV antibody status perceived AIDS as being less severe than men who chose not to learn their antibody status. The authors suggest that this result may reflect the fear associated with HIV/AIDS.

Perceived benefits of HIV testing have consistently been found to be related to HIV testing among MSM and include such benefits as changing sexual practices, receiving treatment if positive, and to better cope with the fear of AIDS. Similarly, Dorr et al. (1999) found

that among individuals presenting to a student health center, those perceiving greater benefits to testing were more likely than those perceiving fewer benefits to have ever tested for HIV.

Among the most common reasons for declining to learn one's test results are concerns that a positive test result would have negative psychological consequences (Lyter et al., 1987), that results would not be useful in changing sexual behavior (Lyter et al., 1987; Zapka, Stoddard, Zorn, McCusker, & Mayer, 1991), that knowledge of serostatus is not useful because there are not effective treatments (Zapka et al., 1991) and that test results are not predictive of progression to AIDS (Lyter et al., 1987). Given the more recent success of antiretroviral therapy in preventing progression to AIDS, the perception that treatments are ineffective may have diminished as a barrier to testing. In fact, perceptions of treatment efficacy have been implicated as a potential explanation for both upward trends of HIV risk behavior since 1996, as well as recent outbreaks of sexually transmitted bacterial infections (Scheer, Chu, Klausner, Katz, & Schwarcz, 2001; Centers for Disease Control and Prevention, 1999a; Centers for Disease Control and Prevention, 1999b; Fox et al., 2001).

### *The Theories of Reasoned Action and Planned Behavior*

Two closely related theories applied widely in HIV research, are the Theories of Reasoned Action (Fishbein et al., 1975) and Planned Behavior (Ajzen et al., 1980; Ajzen, 1985). These expectancy-value models dominated motivational psychology for some time (Kuhl, 1982). In these models, the person intends to perform an action based upon the expectancy for achieving a goal and the extent to which a person values that goal (Kuhl, 1982). The Theory of Reasoned Action (TRA) is based on the assumption that people consider available information and the implications of their actions (Fishbein et al., 1975). The theory further assumes that a person's intention to perform a behavior is the immediate determinant of action. According to the TRA, two factors determine a person's intention; the person's attitude

toward the behavior (i.e., the individual's positive or negative evaluation of performing a behavior), and subjective norms (i.e., the person's perception of social pressures to perform a behavior) (Fishbein et al., 1975). In the TPB, three factors determine a person's intention; the person's attitude toward the behavior, subjective norms, and the degree to which a person feels that they can successfully perform the behavior (Ajzen et al., 1980; Ajzen, 1985).

Jemmott & Jemmott (1991) for example, used the TRA as a conceptual framework to evaluate condom use among African-American women. In this study, a woman's use of condoms was hypothesized to be a function of her intention to use condoms. Intentions to use condoms were assumed to be a function of attitudes (positive or negative) toward using condoms, and perceptions of what significant others think a woman should do with regard to condom use. Thus, if a woman believed that using condoms would protect her from HIV infection and that protection was desirable, her attitude toward using condoms should have been positive. Furthermore, beliefs that a woman's friends would approve of condom use, and that the opinions of friends were important, would also be predictive of intentions to use condoms. These authors found that both positive attitudes toward condom use and perceived subjective norms predicted intentions to use condoms.

In the context of HIV testing, the constructs offered by the theories of Planned Behavior and Reasoned Action may be similarly applied. That is, individuals who perceive HIV testing to be desirable and beneficial, and that their friends would approve of testing, would be expected to have stronger intentions to test for HIV than those who do not. Desirability and benefit may be related to feeling as though one is being proactive with regard to their health and that effective treatments are available for those who do test HIV positive. Perceived social norms regarding HIV testing may be associated with the perceived attitudes of sexual partners and personal friends, as well as the potential for negative social consequences (e.g., stigmatization)



of having HIV. These constructs overlap with Health Belief Model variables of treatment efficacy and subjective norms.

### *Theoretical "Consensus"*

An early theorist workshop addressing HIV risk behavior that included Albert Bandura (Social Learning Theory), Martin Fishbein (Theory of Reasoned Action), Marshall Becker (The Health Belief Model), Harry Triandis (Theory of Subjective Culture and Interpersonal Relations), and Fredric Kanfer (Theory of Self-Regulation and Self-Control) was conducted in October 1991. Together, these five theories represented almost all of the variables that had been utilized in attempts to understand and change a wide variety of behavior. The goal of this workshop was to identify a finite set of variables that should be considered in any behavioral analysis. These theorists combined the common elements of their theories into a "consensus theory" (Fishbein et al., 1991) that focused on an individual's intention to change behavior. Eight variables were identified as critical for understanding behavior: intention, environmental constraints, ability, anticipated outcomes (or attitude); norms, self-standards, emotion, and self-efficacy. Of these, intention, environmental constraints and personal skills were considered necessary and sufficient for producing any behavior. The remaining variables were viewed as influencing the strength and direction of intention.

In a comparative theoretical paper, Weinstein (1993) states that the real goal should not be to decide which theory is best, but to decide which variables and processes improve our understanding of health-protective behavior. Finding that one theory correlates .4 with observed behavior and that another correlates .5 is not nearly as helpful as discovering what features of the theories account for their difference. Weinstein suggests that in addition to examining the overall prediction of behavior, an attempt should be made to understand the relations among

the independent variables and the behavior claimed by the theory to match the relationships actually observed.

In this study, the theories described provided an organizing structure for the development of the project, its conduct, and data analyses. *Empowerment* theory and the general principles of community psychology guided the process of study design and implementation, the *Transtheoretical Model* offered an organizing schema to frame and guide statistical analyses, the *Health Belief Model*, and the Theories of *Reasoned Action* and *Planned Behavior* suggested individual-level constructs useful for understanding HIV testing behavior and the potential use of home testing technology for the detection of HIV antibodies.

#### HOME TESTING TECHNOLOGY - CONSUMER-CONTROLLED TESTING

Technological advances in HIV antibody testing have eliminated the need for venous blood collection and have made possible consumer-collected specimens which then are mailed in for laboratory testing (Gwinn, Redus, Granade, Hannon, & George, 1992; Hannon, Lewis, Jones, & Powell, 1989). Test results and medically directed risk-reduction counseling may then be obtained via telephone (Bayer, Stryker, & Smith, 1995; Home Access Health Corporation, 2003).

A demand for CCT was indicated by a 1992 Health Interview Survey which showed that 42% of individuals at-risk of HIV infection said that they would be likely to use home tests; and of this group, 63% had not been previously tested (Anderson et al., 1992). Respondents in this survey were more interested in CCT if they were; male, younger, nonwhite, lower income, at increased risk for HIV, or perceived themselves to be at-risk of infection. Furthermore, Blacks and Hispanics were more likely than other racial/ethnic groups to say that they would be likely to utilize home testing. This study did not indicate how cost, distribution, or methods for obtaining results might influence the willingness to use home testing.

The market price for home testing kits is \$50, which may be cost-prohibitive for marginalized and stigmatized individuals at-risk of HIV infection, such as, IDUs. With cost as a potential barrier to testing, the goal of increased access to HIV testing for persons most at risk of infection may not be realized (Janssen et al., 2001). Consequently, incorporating CCT technology within the context of existing HIV risk reduction and outreach programs could increase access to testing for high-risk individuals, increase the likelihood that individuals will learn their HIV serostatus, and if infected, receive early antiretroviral therapy and antibiotic prophylaxis for opportunistic infections.

#### THE RESEARCH CONTEXT IN PHILADELPHIA

Philadelphia provided an excellent opportunity for evaluating the public health benefits of CCT due to the social and epidemiologic characteristics of the city, as well as the existing HIV and drug abuse prevention and research infrastructures. Of all positive HIV tests performed at publicly funded CT sites in 1994, Philadelphia ranked seventh in HIV prevalence (3.2%), just behind New York and New Jersey (Fife & Mode, 1992a; Fife & Mode, 1992b). Between 1988 and 1990, the annual estimated AIDS incidence and prevalence per 100,000 people in Philadelphia increased by 21% and 62% respectively, and AIDS prevalence shifted during this time toward lower income census tracts and was estimated to increase by 113% in poor neighborhoods (Fife et al., 1992a; Fife et al., 1992b). In 1994, IDUs became the risk group with the highest proportion of newly diagnosed AIDS cases for the first time in Philadelphia (City of Philadelphia Department of Health, 1994). More recently, the number of IDUs in Philadelphia has been estimated to be 45,260 and HIV incidence among this group has been estimated at 3% per 100 person years (Holmberg, 1996).

## CHAPTER 2

### METHODS

#### *Study Design*

The study employed a randomized prospective field trial design that included both an initial and a one-month follow-up interview. Testing outcomes (HIV testing and obtaining test results) were compared between TCT and CCT, and across three drug abuse prevention/treatment programs; (1) in-treatment methadone maintenance, (2) transitional hospital-based drug detoxification, and (3) out-of-treatment syringe exchange. Theoretical variables potentially related to HIV testing were assessed.

#### *Study Objectives:*

1. To compare the likelihood of HIV testing and obtaining test results between participants randomized to TCT and CCT among methadone maintenance, detoxification, and out-of-treatment drug users
2. To identify sociodemographic, psychosocial, behavioral, and theoretical factors related to HIV testing and obtaining HIV test results
3. To compare satisfaction with the HIV testing process between participants randomized to traditional counseling and testing and consumer-controlled testing

### *Selection of Study Sites*

The social, demographic, and behavioral characteristics of drug users can vary greatly across prevention and treatment environments. For example, out-of-treatment IDUs targeted by HIV prevention outreach programs (e.g., syringe exchange programs) may differ in terms of demographics, HIV risk, and social and behavioral stability from drug users in other environments. Thus, evaluating CCT in a variety of drug prevention and treatment environments will provide a broader perspective as to the determinants of HIV testing and how CCT might be incorporated into HIV and drug abuse prevention and treatment programs. Three study sites serving different segments of the drug use/treatment population; out-of-treatment drug users, methadone patients, and drug detoxification patients participated in the study. Sites were selected by working closely with the Philadelphia Department of Health, Coordinating Office of Drug and Alcohol Abuse Programs (CODAAP).

In 1993, CODAAP received funding to deliver HIV-related services to substance abusers in treatment. These funds supported the development of the “Early Intervention Program” intended to provide HIV prevention counseling, testing, and primary health care services to substance abusers. The Early Intervention Program is comprised of two major elements: on-site HIV pre- and post-test counseling services, and the provision of HIV primary health care. Nineteen (19) testing sites were funded in 1995, which conducted 6,851 pretest counseling sessions, 5,059 HIV antibody tests, and 3,308 post-test counseling sessions. One hundred and ninety-nine (199) individuals tested HIV seropositive, indicating an HIV seroprevalence of 3.9%. Of those individuals tested, 65% received post-test counseling (City of Philadelphia, 1996).

Because of CODAAP's commitment to developing and maintaining a model program of HIV prevention counseling, testing, and primary health care for substance abusers, and because many drug users are unwilling to be tested in traditional clinic-based settings, collaboration with CODAAP strengthened this study and at the same time provided the opportunity to broaden access to HIV testing and counseling for individuals at-risk of HIV infection, and access to treatment for HIV-infected individuals. The following criteria were used during the site selection process:

1. the willingness of the program to participate in the study and to fulfill the requirements of the study protocol;
2. the capacity of the program to accommodate the logistical needs of the study protocol,
3. sufficient client census to recruit study participants with the appropriate demographic characteristics,
4. no mandate of CT as a condition of drug treatment.

Three sites were selected based upon these criteria: Prevention Point Philadelphia, Kensington Hospital, and North Philadelphia Health Systems. Prevention Point Philadelphia enrolled out-of-treatment participants from syringe exchange sites, Kensington Hospital enrolled participants from a hospital-based drug detoxification program, and North Philadelphia Health Systems enrolled participants from a methadone program.

#### *Out-of-Treatment Drug Users - Prevention Point Philadelphia*

Prevention Point Philadelphia (PPP) is a syringe exchange program that has been operating in North Philadelphia since 1991. PPP's mission is to protect the health of habitual drug users and sex industry workers and to prevent the spread of HIV through syringe sharing.

PPP has an empowerment philosophy stressing that the rights of people with addictions includes the ability to protect their own health and the health of their sexual partners and loved ones. PPP offers referrals for drug treatment, HIV testing, and comprehensive health care.

At the time of this study, PPP offered mobile van-based needle exchange services at five sites in Philadelphia. The ethnic composition of PPP's clients was 45% White, 45% African-American, and 10% Latino. "Exchangers" using the program varied widely in age, economic status, and frequency of drug use. In 1994, PPP distributed approximately 750,000 sterile syringes. In addition, PPP conducts shooting gallery outreach and operates a harm reduction "drop-in" center that provides referrals to social, medical, and drug treatment services; offers support groups and educational forums; and has a medical clinic.

#### *Detoxification Participants - Kensington Hospital*

Kensington Hospital is a non-government, not-for-profit, neighborhood hospital established in 1887 to serve the needs of women. The hospital is located in a working class neighborhood in north Philadelphia, where many parts of this community are now experiencing severe economic distress. Once a thriving manufacturing area of the city, few factories remain and unemployment rates are high. The hospital prides itself on being responsive to the needs of the community and because of the high prevalence of substance abuse in the neighborhood, now provides both drug and alcohol detoxification services.

The hospital has 45 inpatient beds, and in 1995 had 2,334 inpatient admissions, and 15,732 outpatient visits. In 1995, 1,831 HIV pre-test counseling sessions were conducted at Kensington Hospital, with 1,002 (55%) of the pre-test counseled patients actually getting tested for HIV. Two hundred and eighty-nine (289; 29%) of the patients tested for HIV returned for post-test counseling and received their HIV test results. Of all HIV tests conducted at

Kensington Hospital in 1995, 48 (5%) were positive for HIV antibodies.

#### *In-Treatment Drug Users - North Philadelphia Health Systems*

North Philadelphia Health Systems (NPHS) is the largest methadone program in the state of Philadelphia. Over 600 individuals are enrolled in the methadone program. In addition to the outpatient methadone program, NPHS has 100 individuals enrolled in drug-free outpatient treatment, and 200 individuals enrolled in intensive outpatient treatment.

In 1995, NPHS/Girard Medical Center conducted 842 HIV pre-test counseling sessions, with 747 (89%) of the pre-test counseled patients choosing to get tested for HIV antibodies. Of these 747 individuals, 404 (54%) returned for post-test counseling and received their HIV test results. Of all HIV tests conducted at Girard Medical Center in 1995, 38 (5%) tested positive for HIV antibodies.

#### *Participants and Eligibility Criteria*

Each of the three study sites set enrollment targets of approximately 200 participants, with the intent to randomly assign 100 individuals to TCT and 100 to CCT. While this number was not ideal from the perspective of conducting within-site analyses based upon power analyses, the overall power to assess the testing outcomes when controlling for site was adequate. To be eligible for the study an individual had to be at least 18 years of age, have never tested positive for HIV antibodies, and have scored below a suicide risk threshold using the Beck Hopelessness Scale (Beck, Steer, Kovacs, & Garrison, 1985; Beck, Brown, Berchick, Stewart, & Steer, 1990). Participants provided informed consent and were paid \$10.00 for the initial interview and \$20.00 for the one-month follow-up interview.



## *Instruments*

### *Brief Screening Instrument*

A brief screening instrument was used to assess interest in HIV testing, study eligibility, and willingness to participate in the study. The screening instrument was self-administered and included items regarding basic demographics, drug treatment status, HIV testing history, interest in HIV testing, hygienic needle behavior, and HIV sex risk behavior. Reasons for refusal were also recorded.

### *Suicide Potential - Beck Hopelessness Scale*

During community forums conducted among members of the target population and consultations with HIV health care professionals who deliver post-test counseling, concern was expressed about potential suicide among home testers who learn their HIV seropositive antibody status over the telephone. Though the risk of suicide related to a de novo HIV positive antibody test results appeared to be low, in response to the concerns elicited during community forums and consultations, the *Beck Hopelessness Scale* (Beck et al., 1985; Beck et al., 1990) was used to assess suicide potential during the pre-enrollment screening. The *Hopelessness Scale* is a 20 item true-false self-report instrument which has been found to differentiate among suicide threateners, attempters, and controls. The *Hopelessness Scale* has three factors and an internal consistency of .93 (Kuder-Richardson). In a 10-year follow-up for eventual suicide, the scale showed a 91% sensitivity for inpatients (Beck et al., 1985) and a 3½-year follow-up study among outpatients showed a 94% sensitivity (Beck et al., 1990). Potential participants who scored a 9 or above on the *Hopelessness Scale* were not eligible for study participation and were referred for psychological services.

In this study, participants had access to 24-hour, manufacture provided, phone counseling. Phone counseling is included with the purchase of a test kit. In addition to these manufacture-provided services, participants were able to call study staff as needed.

#### *HIV Risk Behavior*

The Risk Assessment Battery (RAB) was used as a rapid, private, and minimally intrusive method of assessing both drug and sexual HIV risk behavior (Navaline et al., 1994). The RAB is a self-administered questionnaire that takes less than 15 minutes to administer, has been shown to reliably discriminate between HIV seropositive and seronegative individuals, and has acceptable levels of internal and test-retest reliability (Navaline et al., 1994). In addition to the questions included on the RAB, HIV risk questions identical to those asked during the Home Access pre-test counseling session were included. While these additional questions were somewhat redundant with the RAB, this information allowed for the possibility of a comparison of responses given by participants during a face-to-face versus a telephone counseling session.

#### *HV Testing & Theory-Based Measures Related to Testing*

All participants completed a face-to-face interview about HIV testing that included domains related to past testing experience(s), perceived barriers and benefits to testing, intentions for future testing, and preferred modes of testing and receiving results. Participants were asked to describe how they would cope with a positive test result, and where they might go for help if they tested positive.

Measures based upon theoretical constructs from Stage of Change Theory, the Theories of Reasoned Action/Planned Behavior, and the Health Belief Model were assessed using factor analyses. Internally and conceptually consistent items were used to construct summated rating

scales reflecting each construct.

### *Stages of Change*

The Transtheoretical Model was incorporated so that participants could be categorized according to stages of change in relation to HIV testing behavior according to the a priori schema presented in Table 1. Participants classified in the precontemplation stage are not aware that HIV tests exist, do not recognize any value to being tested for HIV, and do not indicate an intent to test during the next year. Participants classified in the *contemplation* stage are aware of HIV testing, recognize its potential value, report having seriously thought about getting tested, but have not yet made a decision to get tested. In addition to being aware of HIV testing and recognizing its value, participants determined to be in the *preparation* stage express an intention to be tested in the very near future (one month), however, have not yet been tested. Participants classified in the *action* stage perceive that HIV testing is important given their risk behavior and have been tested at least once in the past six months. Finally, participants who continue to engage in risk behavior and who have been frequently tested over the past three years fall within the *maintenance* stage. This classification scheme provides a potential context against which to evaluate constructs from the Theories of Planned Behavior/Reasoned Action and Health Belief Model measures. That is, testing and obtaining one's HIV test results may be more likely among participants who are in the action stage or above.

Table 1

Classification schema for stages of change related to HIV testing

Stage	Aware	Recognize Value	Intention to be tested in the next:			Recent Testing	Frequent Testing
			One Month	Six Months	Twelve Months		
<i>Precontemplation</i>	No	No (Yes?)	No	No	No	No	No
<i>Contemplation</i>	Yes	Yes			No, but considering	No	No
<i>Preparation</i>	Yes	Yes		Yes, near future		No	No
<i>Action</i>	Yes	Yes, important given risk	Yes			Yes, in last 6 months	No
<i>Maintenance</i>	Yes	Yes, continues to engage in risk behavior	Yes			Yes	Yes, in past 3 years

#### *Theories of Reasoned Action/Planned Behavior*

Items based upon the Theories of Reasoned Action/Planned Behavior addressed intentions for testing, attitudes about testing, perceived testing norms and testing self-efficacy. The summated rating scales based upon factor and reliability analyses are presented in Appendix A.

#### *The Health Belief Model*

Questions based upon the Health Belief Model were included addressing perceived susceptibility to HIV infection, severity of consequences, efficaciousness of protective actions (i.e., early intervention), barriers to testing, and cues to action. The summated rating scales based upon factor and reliability analyses are presented in Appendix A.

### *Follow-up Interview*

Participants were scheduled for a one-month follow-up interview at the time of their initial interview. The follow-up interview included questions about pre-test counseling, HIV testing, post-test counseling, HIV risk behavior, satisfaction with the testing and counseling procedures, adverse reactions, intentions for future testing, and preferred modes of testing in the future. If a participant had not completed HIV pre- and post-test counseling by the time they were contacted for their one-month follow-up, they were rescheduled for their follow-up interview at two months from the date of their initial interview. If at two months they had not completed the testing process, they were interviewed using the standard follow-up interview. This procedure was intended to allow those participants who intended but delayed HIV testing to complete the testing process and to receive their HIV test results. If participants did not complete a testing phase (i.e., pre-test, testing, post-test, referral follow-up) information was gathered about the reasons for noncompletion. The RAB was also administered at the follow-up interview to evaluate the relationship of HIV risk behavior to HIV testing outcomes.

### *Procedures*

As a client presented to a study site, they were asked if they had an interest in HIV testing. If interested, a study staff person provided them with a description of the study and obtained basic demographic and HIV risk information. If the individual was not interested in study participation, the reason for refusal was recorded and they were referred to a HIV counseling and testing site.

Individuals who were interested in enrolling were screened for eligibility, and suicide potential was assessed using the Beck Hopelessness Scale. Individuals scoring above a 9 on

the Beck Hopelessness scale were counseled by the study staff and referred to psychological services. Individuals who were not eligible to participate were referred to local agencies that provide HIV CT services.

Informed consent was obtained from all participants prior to enrolling in the study. After consent was obtained, face-to-face interviews were conducted. If an interviewer was unavailable at the time of enrollment, an appointment was made for a future interview in a convenient and safe location, and the participant was given an appointment card. Locator information was obtained from participants, and included address and phone number if available, name and phone number of three friends, and two places where the individual might 'hang out' or spend a significant amount of time. This type of locator information had previously been successfully used to maintain high retention rates in cohort studies targeting similar populations.

#### *Randomization to CT or CCT Conditions*

After the interview, the study staff opened a coded envelope indicating the random assignment of the participant to either the TCT or CCT conditions. Participants randomized to the TCT condition were referred to a confidential testing site, or if testing was provided in-house (i.e., detoxification program), a referral was made to the in-house HIV testing staff. A release of information form was obtained from the participant allowing the study staff to obtain the HIV testing information from the TCT site to which the participant was referred. Participants randomized to the CCT condition received a home test kit (Home Access System™) and instructions on using the home collection kit, which included a discussion of contraindications, precautionary measures, product limitations, manufacture's informed consent, registering the Home Access code number (necessary for obtaining HIV test results), mailing the specimen,

and obtaining the result. The Home Access code number was recorded in the participant's study record for subsequent retrieval of database records from Home Access. If desired, all participants were able to contact a study staff person for face-to-face counseling, to answer questions, or for service referrals. After these procedures were completed, an appointment was scheduled for the follow-up interview and participants were paid \$10.

#### *Follow-up Interview*

At the follow-up visit participants completed a face-to-face interview which included questions regarding satisfaction with the testing process to which they were randomized, problems they encountered in the testing process, the type of information provided to them during pre- and post-test counseling, their intentions for future HIV testing, referrals provided and follow-through with these referrals. In addition to these questions, the RAB was also administered.

After the interview, any questions participants had were addressed and referrals were provided as necessary. Participants were then paid \$20.00 for their participation and were provided with a phone number to call if they had future questions.

#### *Data Exchange with Home Access & Confidential CT Sites*

The retrieval of testing data was considered optimal from both the Home Access Health Corporation for participants randomized to the CCT and from confidential testing sites for participants randomized to TCT. A signed release of information form authorized study staff to receive participant data from Home Access Health Corporation and confidential CT sites. These data included demographics and HIV risk behavior information, whether the participant

received pre-test counseling, was HIV tested, received post-test counseling and their HIV test results. HIV test results were also obtained.

Data records from the Home Access Health database were extracted using kit identification numbers. After all follow-up visits were completed; Home Access was sent an electronic list of study participant test kit numbers to retrieve the appropriate computerized records. These data records were merged with study interview data. Data from confidential testing sites were retrieved in a similar fashion; however, participant name was used to retrieve records at the confidential CT sites. Immediately after the testing data was obtained from the confidential CT sites, the testing data were indexed using study identification number, the name identifier was then deleted, and the link between name and study identifier stored in a separate locked file cabinet as described in the records management section. Because it was anticipated that these data may not be reliably retrieved from testing sites for multiple reasons, participants also self-reported the testing outcome data during their follow-up interview.

### *Data Analyses*

Standard bivariate analyses (Chi-square, t-tests, and ANOVA) were used to evaluate selection differences among those who enrolled in the study and those who refused to participate. These analyses included comparisons of demographic, sexual and drug-related HIV risk, history of sexually transmitted diseases, Beck Hopelessness Scale scores, and HIV testing history between study participants and non-participants. Multivariate logistic regression analysis was then conducted to model study enrollment using the correlates identified in the bivariate analyses. This same approach was also used to assess study retention.

Randomization to TCT and CCT was assessed by comparing these groups across demographic, HIV risk, and theoretical factors. Differences among sites were also evaluated



across demographic, sexual and drug-related HIV risk, history of sexually transmitted diseases, Beck Hopelessness scores, and HIV testing history to better understand the contextual factors associated with treatment context.

### *Testing Outcome Analysis*

Subsequent to these analyses of study enrollment, randomization, site differences, and retention, bivariate analyses were also conducted to evaluate the association of study site, demographic, risk behavior, and theoretical variables to HIV testing outcome variables. Variables associated with testing outcomes in these bivariate analyses were retained for multivariate logistic regression analyses. Hierarchical logistic regression was used to evaluate the unique effect of testing method above and beyond the effects of study site, demographic, and theoretical variables. For example, to evaluate the effect of testing method on being tested for HIV, site and demographic variables were entered in block one, health status variables in block two, HIV risk variables in block three, theoretical variables in block four, and testing method in block five. The R<sup>2</sup>L statistic was calculated for each block of variables indicating the magnitude of the effect for the block relative to the base model. R<sup>2</sup>L is an analog to  $\Delta R^2$  in multiple regression analysis. The unadjusted and adjusted odds ratios were calculated for the bivariate and multivariate analyses respectively.

### *Records Management*

Since participants were interviewed on more than one occasion, it was necessary to maintain data that permitted site researcher staff to contact participants. All participant locator data was stored in secure areas and in a locked file cabinets. Access to the locked files containing locator data was limited to the site coordinator, projected coordinator, and principle

investigator. Computerized and hard copy locator data was kept separate from interview and HIV test data, which were indexed by study identifier code only.

### *Human Subjects*

Written ethical approval was obtained from Institutional Review Boards at the Centers for Disease Control and Prevention, the University of Pennsylvania, and the City of Philadelphia's Department of Public Health. This research involved the completion of interviews from individuals who are members of the injection drug using community. Individuals who were interviewed were fully informed of the purpose of the study, and the potential risks. The consent and release of information form(s) were approved by appropriate IRBs prior to use.

## CHAPTER 3

### RESULTS

#### SCREENING AND ENROLLMENT

Overall, 645 individuals were screened for study participation. Of these, 532 (83%) were eligible to enroll in the study based upon the Beck Hopelessness Scale eligibility criteria. Of the 532 eligible individuals, 489 (92%) enrolled in the study.

Participants were more likely to be enrolled from the Kensington Detoxification Hospital program than from the other sites, and approximately three quarters of participants were male (Table 2). Those enrolled were primarily African American and Caucasian, and most participants had a high school education or less. Almost half of the participants reported their primary source of income to be Welfare, over 80% reported an annual income of less than \$10,000 per year, and the majority reported Medicaid to be their source of health insurance.

Table 2

Demographics of Individuals Enrolled in the Study

Variable	N	%	M	(SD)
<b>Site</b>				
Kensington	199	41		
Prevention Point	128	26		
ACT	161	33		
<b>Sex</b>				
Male	348	71		
Female	140	29		
<b>Race</b>				
African-American	234	48		
Latino/Hispanic	46	9		
Caucasian	205	42		
Other	4	1		
<b>Education</b>				
< HS	193	40		
HS	280	57		
Any College	15	3		
<b>Primary Source of Income</b>				
Full time	48	10		
Part time	40	8		
Welfare	219	45		
Family/friend	19	4		
Hustling	66	14		
Other	96	20		
<b>Income</b>				
Under \$10,000	398	81		
≥\$10,000	94	19		
<b>Living Situation</b>				
Own House	187	39		
With friend	206	42		
Rented Room	33	7		
Homeless	37	8		
Other	23	5		
<b>Medical Insurance</b>				
Private health plan	14	3		
Medicaid	249	53		
Social security disability	31	7		
Medicare	34	7		
Military	2	.4		
Other insurance	144	30		
Age			40.4	75.9
Beck Hopelessness Scale			3.98	3.09

### *Assessment of Selection Biases*

Differences were observed between those enrolled and not enrolled in the study. Fewer participants than expected were enrolled from the Prevention Point Syringe Exchange Program than from the Kensington Detoxification Hospital or the ACT methadone maintenance program (Table 3). African-Americans were more likely to enroll than were persons from other racial/ethnic groups. Individuals who had full-time jobs were more likely to enroll than were individuals whose primary source of income was from other sources, whereas those who reported “hustling” as their primary source of income were least likely to enroll.

Persons who enrolled in the study were less likely than those who did not, to report injecting drugs in the 6 months prior to study enrollment (Table 4), however, a significant majority of those enrolled did report injecting drugs, and thus were at significant risk of HIV infection. Furthermore, almost half of the individuals screened and enrolled in the study reported sharing injection equipment with drug using partners, underscoring the risk of HIV infection in this population. Study enrollees were less likely than non-enrollees to report having been diagnosed with hepatitis B/C, further indicating that non-enrollees were at greater drug-related risk of HIV infection than were enrollees. Very few men reported having sex with other men and few women reported engaging in anal sex with male partners, indicating that the primary risk of HIV in this population was related to injecting drug use. Most individuals screened for the study reported previously being tested for HIV, with no differences in prior testing between those enrolled and those who were not.

Table 3

## Demographic Differences between Individuals Enrolled and not Enrolled in the Study

Variable	Screening Group				$\chi^2/t$	<i>p</i>
	Not Enrolled		Enrolled			
	N M	% SD	N M	% SD		
Site						
Kensington	53	34	199	41	14.9	.001
Prevention Point	66	42	128	26		
ACT	37	24	161	33		
Sex						
Male	103	66	348	71	1.6	.21
Female	53	34	140	29		
Race						
African-American	46	30	234	48	16.9	.001
Latino/Hispanic	19	12	46	9		
Caucasian	88	56	205	42		
Other	3	2	4	1		
Education						
< HS	65	42	193	40	0.9	.65
HS	85	55	280	57		
Any College	5	3	15	3		
Primary Source of Income						
Full time	4	3	48	10	17.8	.003
Part time	9	6	40	8		
Welfare	61	40	219	45		
Family/friend	5	3	19	4		
Hustling	35	23	66	14		
Other	40	26	96	20		
Income						
Under \$10,000	136	88	398	81	3.4	.07
\$10,000	19	12	94	19		≥
Living Situation						
Own House	49	32	187	39	7.6	.11
With friend	63	41	206	42		
Rented Room	13	8	33	7		
Homeless	22	14	37	8		
Other	8	5	23	5		
Medical Insurance						
Private health plan	2	1	14	3	3.43	.64
Medicaid	70	48	249	53		
Social security disability	13	9	31	7		
Medicare	11	7	34	7		
Military	0	0	2	0		
Other insurance	49	34	144	30		
Age (Mean,SD, <i>t</i> )	41.5	24.1	40.4	75.9	0.59	.50
Beck Hopelessness Scale (Mean, SD, <i>t</i> )	11.5	4.7	3.98	3.09	1.72	.09

Table 4

## HIV Risk Factors and HIV Testing of Individuals Enrolled and not Enrolled

Risk factor	Screening Group				$\chi^2$	<i>p</i>
	Not enrolled		Enrolled			
	N	%	N	%		
<b>Drug Related Risk</b>						
Injected drugs last 6 months	121	77.6	329	67.4	5.78	.016
Shared (syringe, cooker, cotton, rinse water)	76	48.7	209	42.7	1.71	.191
<b>Sexual Risk</b>						
Men reporting sex with male <sup>a</sup>	1	0.6	4	0.8	0.46	.830
Women reporting anal sex with male partner <sup>a</sup>	0	0.0	5	1.0	1.61	.34
<b>STDs</b>						
Hepatitis B/C	31	20.0	57	11.7	6.89	.009
Gonorrhea <sup>a</sup>	1	0.6	4	0.8	0.46	.830
Syphilis <sup>a</sup>	3	1.9	3	0.6	2.22	.14
Ever tested for HIV	132	84.6	420	85.9	0.16	.69

Note. Limited risk assessment at screening due to IRB restrictions

<sup>a</sup> Fisher's Exact Test

### *Multivariate Assessment of Study Enrollment*

Multivariate logistic regression analysis that included those variables significantly related to study enrollment in the bivariate analyses indicated that study site, race, and employment status were the primary factors related to study enrollment. The adjusted odds ratios and associated confidence intervals are presented in Table 5.

Table 5  
Factors Related to Study Enrollment: Multivariate Logistic Regression Results

Variable	Adjusted Odds Ratio	95% CI
<b>Study Site</b>		
Kensington (reference)	-	- -
Prevention Point	0.52	0.33 - 0.84
ACT	1.17	0.71 - 1.95
<b>Race</b>		
African-American (reference)	-	- -
Latino/Hispanic	0.42	0.27 - 0.64
Caucasian	0.34	0.17 - 0.70
Other	0.25	0.50 - 1.24
<b>Primary Source of Income</b>		
Full time (reference)	-	- -
Part time	0.40	0.11 - 1.44
Welfare	0.31	0.10 - 0.91
Family/friend	0.30	0.07 - 1.25
Hustling	0.18	0.06 - 0.57
Other	0.21	0.07 - 0.63



### *Randomization Assessment*

Randomization to consumer-controlled testing or traditional counseling and testing resulted in nearly identical groups. Participants randomized to the two study arms did not differ with regard to demographics (Table 6), sex or drug risk variables assessed at screening or enrollment (Tables 7/8), history of sexually transmitted infections, previous HIV testing experience (Table 7), or most theoretical variables (Table 9). However, the perception that testing would affect personal relationships did differ by group, with the TCT group being somewhat more likely than those randomized to CCT to perceive that testing might negatively impact their personal relationships.

Table 6

## Randomization Assessment: Demographics by Study Arm

Variable	Study Arm/Testing Method				$\chi^2/t$	<i>p</i>
	Consumer-Controlled		Traditional			
	N M	% SD	N M	% SD		
<b>Site</b>						
Kensington	102	43	97	39	0.73	.70
Prevention Point	60	25	68	27		
ACT	77	32	84	34		
<b>Sex</b>						
Male	169	70	179	72	0.19	.67
Female	71	30	69	28		
<b>Race</b>						
African-American	109	45	125	50	1.3	.72
Latino/Hispanic	25	10	21	8		
Caucasian	104	43	101	41		
Other	2	1	2	1		
<b>Education</b>						
< HS	90	38	103	41	1.11	.57
HS	101	42	105	42		
College	48	20	41	17		
<b>Primary Source of Income</b>						
Full time	22	9	26	11	6.6	.25
Part time	23	10	17	7		
Welfare	111	46	108	44		
Family/friend	13	5	6	2		
Hustling	31	13	35	14		
Other	40	17	56	23		
<b>Income</b>						
Under \$10,000	198	83	200	80	0.52	.47
≥ \$10,000	41	17	49	20		
<b>Living Situation</b>						
Own House	89	38	98	40	1.68	.80
With friend	104	44	102	42		
Rented Room	18	8	15	6		
Homeless	17	7	19	8		
Other	9	4	14	6		
<b>Medical Insurance</b>						
Private health plan	6	3	8	3	3.16	.68
Medicaid	117	51	132	54		
Social security disability	13	6	17	7		
Medicare	21	9	13	5		
Military	1	1	1	0		
Other insurance	71	31	73	29.9		
<b>Age (Mean,SD, t)</b>						
	40.5	9.3	40.3	9.3	0.20	.91
<b>Beck Hopelessness Scale (Mean, SD, t)</b>						
	3.97	3.21	3.96	2.94	0.02	.98

Table 7

## Randomization Assessment: HIV Risk Factors by Study Arm (screening data)

Risk Factor	Study Arm/Testing Method				$\chi^2$	<i>p</i>
	Consumer-Controlled		Traditional			
	N	%	N	%		
<b>Drug Related Risk</b>						
Injected drugs last 6 months	157	66	172	69	0.63	.43
Shared (syringe, cooker, cotton, rinse water)	63	26	53	21	1.67	.20
<b>Sexual Risk</b>						
Sex with male partner	62	26	66	27	0.13	.91
Anal Sex with male partner	11	5	17	7	0.78	.38
Sex with female partner	151	63	169	68	1.19	.28
<b>STDs</b>						
Hepatitis B/C	33	14	24	10	2.45	.29
Gonorrhea <sup>a</sup>	4	2	0	0	4.20	.06
Syphilis <sup>a</sup>	0	0	3	1	2.90	.25
Ever tested for HIV	209	87	211	85	0.55	.46

<sup>a</sup>Fisher's exact test

Table 8

## Randomization Assessment: HIV Risk Factors by Study Arm (Risk Assessment Battery)

Risk Factor	Study Arm/Testing Method				$\chi^2$  t	p
	Consumer-Controlled		Traditional			
	N M	% SD	N M	% SD		
<b>Risk Assessment Battery (Mean,SD, t)</b>						
Sex Risk	4.91	3.28	5.36	2.96	1.55	.12
Drug Risk	5.91	5.81	5.69	5.98	0.41	.69
Total RAB Score	10.86	7.49	11.12	7.54	0.38	.70
<b>Drug Risk Variables</b>						
Injected in Past 6-Months	156	66	171	69	0.54	.46
Shared Needles (past 6-months)	62	26	68	27	0.12	.73
Injected Heroin (past month)	131	58	147	62	0.52	.47
Injected Cocaine (past month)	56	25	61	26	0.03	.88
Injected Amphetamine (past month)	16	7	11	5	1.33	.25
<b>Sex Risk Variables</b>						
Paid to have sex	11	5	18	7	1.54	.22
Men reporting sex with men						
Sex with HIV+ partner	11	5	18	7	1.50	.22

Note. Percents represent % "yes"

Table 9  
Randomization Assessment: Theoretical Factors by Study Arm

Variable	Study Arm/Testing Method				$t/\chi^2$	$p$
	Consumer-Controlled		Traditional			
	M N	SD %	M N	SD %		
<b>Beck Hopelessness Scale</b>	3.97	3.22	3.96	2.94	0.02	.98
<b>Health Belief Model</b>						
Perceived susceptibility	2.96	1.10	2.90	1.10	0.53	.59
Treatment efficacy/ Perceived severity	3.95	0.88	3.93	0.95	0.14	.89
Personal efficacy (coping)	2.66	1.29	2.62	1.29	0.34	.73
<b>Theory Reasoned Action/ Planned Behavior</b>						
Intentions to test (% Yes) in next 30 days	103	43.1	105	42.2	0.04	.84
Perceived norms	3.45	0.77	3.43	0.81	0.01	.93
Personal health (feel good)	5.70	0.90	5.70	0.87	0.01	.99
Social consequences (stigma)	2.20	0.92	2.36	0.98	1.86	.06
Personal relationships	1.83	0.89	2.12	1.03	3.33	.001
<b>Distrust of government</b>	2.51	1.30	2.67	1.22	1.46	.14

### *Differences among Sites/Drug Treatment Context*

Participant demographics, HIV risk factors, and theoretical measures differed substantially across site/treatment context. Syringe exchange participants were more likely than those in detoxification or methadone maintenance to be African American, to report “hustling” as a primary source of income, and to report an income in excess of \$10,000 per year; however, syringe exchange participants were also less likely to report living in their own house and more likely to report being homeless (Table 10). Syringe exchange participants had higher scores on the RAB sex and drug risks scales, and were more likely than participants from the other sites to have injected drugs in the past six months including heroin, cocaine, and amphetamines; and to have shared injecting equipment (Table 11). Furthermore, participants from the syringe exchange site were more likely than those from the other sites to have been paid for sex, to have had sex with a partner known to be HIV infected, and to report a recent STD (Table 12). Syringe exchange participants also had higher Beck Hopelessness Scale scores, perceived themselves more likely to become HIV infected in the future, and were more likely to report a recent intention to be tested for HIV (Table 13).

Participants from the detoxification program were younger, more likely to live with a friend, and had lower Beck Hopelessness scores than did participants from the other sites (Table 10). These participants were also somewhat less likely to report having been diagnosed with hepatitis B/C. Detoxification participants had higher personal self-efficacy scores regarding their ability to cope with HIV infection should they test HIV antibody positive and had lower Beck Hopelessness Scale scores than participants from the other sites (Table 13).

Methadone maintenance program participants were more likely than those from the other sites to be female, of Hispanic ethnicity, to report Welfare as their primary source of

income and their income to be less than \$10,000 per year, and to be receiving Medicaid (Table 10). However, participants from the methadone program were also more likely than those from the other sites to report living in their own house. With regard to HIV risk, participants from the methadone program had the lowest sex and drug RAB scores among the sites and were less likely to have injected heroin, cocaine, and amphetamines than were participants in the other programs (Table 11). Furthermore, methadone participants perceived themselves to be less susceptible to HIV infection and were not as likely to report a recent intention to test for HIV antibodies than were participants from the other programs (Table 13).

Table 10  
Demographics by Study Site/Treatment Context

Variable	Study Site/ Drug Treatment Context						$\chi^2/F$	<i>p</i>	
	Syringe Exchange		Detox		Methadone Maintenance				
	N M	% SD	N M	% SD	N M	% SD			
Sex									
Male	152	76	188	76	111	56	25.3	.000	
Female	47	24	60	24	86	44			
Race									
White	80	40	122	49	91	46	26.3	.000	
Black	110	55	96	39	74	38			
Hispanic	7	4	29	12	29	15			
Other	3	2	1	0	3	2			
Education									
<High school	44	33	80	41	69	43	5.5	.231	
High school	59	44	86	44	61	38			
Any College	29	15	30	23	29	18			
Primary source of income									
Full time job	7	4	33	13	12	6	104.0	.000	
Part time job	17	9	23	9	9	5			
Welfare	75	38	98	40	107	54			
Family/friend	4	2	18	7	2	1			
Hustling	59	30	38	15	4	2			
Other	36	18	37	15	63	32			
Income									
Under \$10,000	142	72	116	87	140	88	18.1	.000	≥
\$10,000	54	28	17	13	19	12			
Living Situation									
Own House	38	29	69	39	80	50	42.4	.000	With
friend	55	41	91	47	60	38			
Rented Room	10	8	8	4	15	9			
Homeless	21	16	15	8	0	0			
Other	9	7	10	5	4	3			
Medical Insurance									
Private health plan	8	7	2	1	4	3	108.5	.000	
Medicaid	47	39	79	41	123	79			
Social security disability	9	7	5	3	16	10			
Medicare	5	4	23	12	6	4			
Military	2	2	0	0	0	0			
Other insurance									
Age (Mean,SD, F)	43.8	7.99	36.5	9.52	42.9	8.42	38.5	.000	
Median	44.3		36.1		44.1				
Beck Hopelessness (M, SD,F)	4.87	3.76	3.55	2.41	3.72	3.05	8.24	.000	



Table 11  
HIV Risk Factors (RAB data) by Study Site/Treatment Context

Risk Factor	Drug Treatment Context						$\chi^2$  F	p
	Syringe Exchange		Detox		Methadone Maintenance			
	N M	% SD	N M	% SD	N M	% SD		
<b>Risk Assessment Battery (M,SD,F)</b>								
Sex Risk	6.0	3.72	5.4	2.97	4.43	2.44	14.3	.000
Drug Risk	8.5	5.98	5.7	5.94	3.62	4.82	26.9	.000
Total RAB Score	14.5	8.32	11.3	7.07	7.76	5.74	32.4	.000
<b>Drug Risk Variables</b>								
Injected in Past 6-Months	114	87	118	60	94	59	32.4	.000
Shared Needles (past 6-months)	45	35	52	27	33	21	7.02	.03
Injected Heroin (past month)	103	79	103	60	71	45	34.5	.000
Injected Cocaine (past month)	55	42	43	25	19	12	34.3	.000
Injected Amphetamine (past month)	17	13	6	4	4	3	17.1	.000
<b>Sexual Risk Variables</b>								
Paid to have sex	19	15	5	3	5	3	23.3	.00
Men Reporting Sex with Men	4	12	1	5	0	0	3.4	.18
Sex with HIV+ Partner	19	15	5	3	5	3	23.3	.000

Note. Percents represent % "yes"

Table 12  
 Reported STDs and Previous HIV Testing by Study Site/Treatment Context

Risk Factor	Site/Drug Treatment Context						$\chi^2$	<i>p</i>
	Syringe Exchange		Detox		Methadone Maintenance			
	N	%	N	%	N	%		
STDs								
Hepatitis B/C	22	17	16	8	19	12	5.4	.07
Gonorrhea	3	2	1	1	0	0	4.90	.09
Syphilis	3	2	0	0	0	0	8.03	.02
Any STD								
Ever tested for HIV	114	86	164	84	142	89	2.34	.31

Table 13  
Theoretical Factors by Site/Treatment Context

Variable	Study Site/Drug Treatment Context							
	Syringe Exchange		Detox		Methadone Maintenance		$F \chi^2$	$p$
	M N	SD %	M N	SD %	M N	SD %		
Beck Hopelessness Scale	4.92	3.79	3.55	2.41	3.72	3.72	8.9	.000
Fear Government	2.68	1.04	2.61	1.08	2.72	1.06	0.53	.59
Health Belief Model								
Perceived susceptibility	3.20	1.10	3.0	1.03	2.63	1.12	10.4	.000
Treatment efficacy/severity	3.92	0.87	3.92	0.97	3.99	0.92	0.35	.71
Personal efficacy	2.49	1.26	2.88	1.30	2.48	1.25	5.7	.004
Theory Reasoned Action/ Planned Behavior								
Intentions (n/%)	85	64	71	36	52	33	34	.000
Personal health	5.73	0.82	5.65	0.90	5.74	0.92	0.59	.56
Social consequences	2.32	0.98	2.23	0.99	2.31	1.01	0.46	.63
Personal relationships	1.88	0.87	2.09	1.01	1.93	1.01	2.28	.10
Distrust of government	2.60	1.21	2.61	1.31	2.55	1.25	0.13	.88

### *Participant Retention and Attrition*

Of the 489 participants who were enrolled in the study, 417 (86%) completed their follow-up visit, and 71 (15%) did not return for this visit. There was no difference in follow-up between participants randomized to TCT and CCT ( $\chi^2=0.21, p \leq 0.65$ ). However, several differences were observed between participants retained and not retained in the study with regard to demographic, HIV risk behavior, and theoretical variables. Participants who were not retained in the study were more likely to have been enrolled from the detoxification hospital, and less likely to report being on Welfare and to report Medicaid as their health insurance (Table 14). Furthermore, participants who did not return for their follow-up visit had higher RAB drug and total risk scores and were more likely to report recent injection of cocaine than were participants who were retained in the study (Table 15). Lastly, participants who were retained in the study were more likely than those who were not, to report that HIV testing is perceived to be an important part of their personal health strategy (Table 16).

Table 14

## Retention Status by Demographic Variables

Variable	Retention Status				$\chi^2/t$	<i>p</i>
	Retained		Not Retained			
	N M	% SD	N M	% SD		
<b>Site</b>						
Kensington	152	37	49	69	32.5	.00
Prevention Point	110	26	17	24		
ACT	155	37	5	7		
<b>Sex</b>						
Male	294	71	53	75	0.46	.49
Female	122	29	18	25		
<b>Race</b>						
African-American	201	48	33	47	2.72	.44
Latino/Hispanic	42	10	4	6		
Caucasian	170	41	34	48		
Other	4	1	0	0		
<b>Education</b>						
< HS	171	41	22	31	2.41	.49
HS	233	56	46	66		
College	13	4		3		
<b>Primary Source of Income</b>						
Full time	38	9	10	14	11.4	.04
Part time	34	8	6	9		
Welfare	193	46	26	37		
Family/friend	14	3	5	7		
Hustling	51	12	15	21		
Other	87	21	8	11		
<b>Income</b>						
Under \$10,000	342	82	56	79	0.40	.53
≥ \$10,000	75	18	15	21		
<b>Living Situation</b>						
Own House	89	38	98	40	1.68	.80
With friend	104	44	102	42		
Rented Room	18	8	15	6		
Homeless	17	7	19	8		
Other	9	4	14	6		
<b>Medical Insurance</b>						
Private health plan	11	3	3	4	14.1	.02
Medicaid	224	55	25	37		
Social security disability	28	7	2	3		
Medicare	25	6	9	13		
Military	2	1	0	0		
Other insurance	115	28	29	43		
<b>Age (Mean,SD, t)</b>						
	40.8	9.35	38.9	9.61	1.80	.72
<b>Beck Hopelessness Scale (Mean, SD, t)</b>						
	3.94	3.11	5.58	4.09	1.64	.00

Table 15

## Retention Status by HIV Risk Variables

Risk Factor	Retention Status				$\chi^2$	<i>t</i>	<i>p</i>
	Retained		Not Retained				
	N M	% SD	N M	% SD			
<b>Risk Assessment Battery (<i>M, SD, t</i>)</b>							
Sex Risk	5.10	3.06	5.41	3.50	0.71		.48
Drug Risk	5.52	5.68	7.48	6.90	2.19		.03
Total RAB Score	10.64	7.22	13.15	8.82	2.18		.03
<b>Drug Risk Variables</b>							
Injected in Past 6-Months	277	67	49	69	0.14		.71
Shared Needles (past 6-months)	109	26	21	30	0.43		.51
Injected Heroin (past month)	233	59	44	66	1.11		.29
Injected Cocaine (past month)	93	24	24	36	4.62		.03
Injected Amphetamine (past month)	23	6	4	6	0.00		.96
<b><u>Sex Risk Variables</u></b>							
Paid to have sex	24	6	5	7	0.17		.68
Men reporting sex with men	4	6	1	17	1.11		.29
Sex with HIV+ partner	24	6	5	7	0.17		.68

Table 16  
Retention Status by Theoretical Variables

Variable	Study Arm/Testing Method				$t$ / $\chi^2$	$p$
	Retained		Not Retained			
	M N	SD %	M N	SD %		
<b>Beck Hopelessness Scale</b>	3.98	3.12	3.92	2.79	0.10	.92
<b>Health Belief Model</b>						
Perceived susceptibility	2.94	1.11	2.89	1.07	0.35	.73
Treatment efficacy/ Perceived severity	3.95	0.93	3.91	0.85	0.34	.74
Personal efficacy (coping)	2.64	1.29	2.65	1.29	0.05	.96
<b>Theory Reasoned Action/ Planned Behavior</b>						
Intentions to test (% Yes) in next 30 days	177	42	31	44	0.04	.85
Perceived norms	3.46	0.80	3.35	0.75	1.08	.28
Personal health (feel good)	5.74	0.90	5.48	0.75	2.61	.01
Social consequences (stigma)	2.26	0.95	2.41	0.96	1.28	.20
Personal relationships	1.96	0.96	2.12	1.06	1.13	.19
<b>Distrust of government</b>	2.57	1.28	2.69	1.17	0.72	.47

### *Multivariate Assessment of Study Retention*

Among those variables shown to be related to study retention in the bivariate analyses, only study site and RAB drug risk score retained their association in the multivariate logistic regression analysis. The adjusted odds ratios and associated confidence intervals are presented in Table 17.

Table 17  
Factors Related to Study Retention: Multivariate Logistic Regression Results

Variable	<i>Adjusted Odds Ratio</i>	<i>95% CI</i>
Study Site		
Kensington (reference)	-	- -
Prevention Point	0.28	0.15 - 0.52
ACT	0.08	0.04 - 0.20
RAB Drug Risk Score	1.05	1.01 - 1.10



### *HIV Testing Outcomes*

Participants randomized to consumer-controlled and traditional counseling and testing differed with regard to being tested while in the study (Table 18). Participants in the CCT arm were 2.2 times more likely (95% CI= 1.38-3.55) than those in the TCT arm to report having tested for HIV antibodies at the follow-up visit. However, no difference by study arm was observed with regard to receiving HIV test results or HIV antibody status.

Table 18  
Testing Outcomes by Study Arm

Variable	Study Arm				$\chi^2$	<i>p</i>
	Consumer-Controlled		Traditional			
	N	%	N	%		
HIV Testing						
No	34	16	64	30	11.4	.001
Yes	174	84	147	70		
Received HIV test results						
No	37	21	33	23	0.12	.72
Yes	137	79	111	77		
HIV serologic results						
Negative	128	85	109	80	5.26	.15
Positive	6	4	8	6		
Indeterminate	3	2	0	0		
Don't know	13	9	19	14		

### *Bivariate Associations of HIV Testing*

Bivariate analyses of HIV testing revealed that testing differed by demographic, health status, HIV risk, and theoretical variables. Demographically, testing in the study was related to study site, age, primary source of income, health insurance status, and a history of homelessness (Tables 19/20). Testing was also associated with health-related variables including having had a STD or hepatitis B, reporting a recent visit to a hospital emergency room, or having seen a health care provider in the recent past (Table 21). Sex and drug risk behaviors were also indicated by the bivariate analyses to be related to HIV testing as indicated by RAB scores, recent injection of drugs, the sharing of injection equipment, use of heroin and cocaine, being paid to have sex, and having an HIV seropositive sex partner (Table 22). Several theoretical variables were also indicated to be related to HIV testing including perceived susceptibility/risk of HIV, perceived efficacy of available treatments for HIV infection, and recent intentions to test for HIV (Table 23).

Table 19  
Demographic Variables by Testing Outcome (1)

Variable	Testing Outcome				$\chi^2$  t	p
	Tested		Not Tested			
	N M	% SD	N M	% SD		
<b>Site</b>						
Prevention Point	112	35	4	4	36.4	.00
Kensington	99	31	49	50		
ACT	109	34	45	46		
<b>Sex</b>						
Male	225	71	70	71	0.03	.87
Female	94	30	28	29		
<b>Race</b>						
African-American	148	46	53	54	2.82	.42
Latino/Hispanic	34	11	9	9		
Caucasian	134	42	36	37		
Other	4	1	0	0		
<b>Education</b>						
<High school	125	73	47	27	2.45	.12
>= High school	182	78	51	22		
<b>Primary Source of Income</b>						
Full time	25	8	13	13	14.4	.014
time	30	9	4	4		Part
Welfare	152	485	42	43		
Family/friend	6	2	8	8		
Hustling	40	13	11	11		
Other	67	21	20	20		
<b>Income</b>						
Under \$10,000	274	84	74	76	3.73	.053
\$10,000	52	16	24	24		≥
<b>Living Situation</b>						
Own House	122	38	46	48	7.31	.121
With friend	141	44	42	43		
Rented Room	20	6	5	5		
Homeless	22	7	3	3		
Other	19	6	1	1		
<b>Medical Insurance</b>						
Private health plan	9	3	2	2	1.50	.91
Medicaid	171	56	53	54		
Social security disability	22	7	6	6		
Medicare	20	7	6	6		
Military	2	1	0	0		
Other insurance	84	27	31	32		
Age(Mean,SD, t)	41.3	9.09	39.2	10.0	1.97	.05
Beck Hopelessness Scale (Mean, SD, t)	4.02	3.18	3.66	2.88	1.01	0.314

Table 20  
Demographic Variables by Testing Outcome (2)

Variable	Testing Outcome				$\chi^2$	<i>p</i>
	Tested		Not Tested			
	N	%	N	%		
Have Health Insurance	267	84	93	95	7.7	.006
Ever Homeless	167	52	27	28	18.3	.000

Table 21  
Health-Related Variables by Testing Outcome

Variable	HIV Testing				$\chi^2$	<i>p</i>
	Tested		Not Tested			
	N	%	N	%		
Ever STD	137	43	29	30	5.48	.019
Ever Hepatitis -C	55	17	10	10	2.50	.114
Ever Hepatitis B	58	18	7	7	6.84	.009
Emergency Room Visit	94	29	18	18	4.63	.031
Hospitalized	42	13	7	7	2.59	.11
Seen Health Provider	199	62	50	51	3.89	.049

Table 22  
Sex and Drug Risk Variables (RAB) By Testing Outcome

Risk Variable	HIV Testing				$\chi^2$  t	p
	Tested		Not Tested			
	N M	% SD	N M	% SD		
<b>Risk Assessment Battery</b>						
Sex Risk	5.24	3.19	4.61	2.54	1.78	.076
Drug Risk	6.20	5.91	3.26	4.10	5.40	.000
Total RAB Score	11.47	7.60	7.87	4.96	5.30	.000
<b>Drug Risk Variables</b>						
Injected in Past 6-Months (N/%)	227	71.4	50	51.0	13.9	.000
Shared Needles (past 6-months)	93	29.2	16	16.3	6.5	.011
Injected Heroin (past month)	188	62.0	45	47.9	5.9	.015
Injected Cocaine (past month)	80	26.4	13	13.8	6.3	.012
Injected Amphetamine (past month)	21	6.9	2	2.1	3.0	.82
<b>Sex Risk Variables</b>						
Paid to have sex	24	7.6	0	0.0	7.88	.002
Men Reporting Sex with Men	9	4.0	1	1.4	1.07	.461
Sex with HIV+ Partner	24	7.6	0	0.0	7.88	.002

Table 23

## Theoretical Variables by Testing Outcome

Theoretical Variable	HIV Testing				<i>t</i>   $\chi^2$	<i>p</i>
	Tested ( <i>n</i> =320)		Not Tested ( <i>n</i> =98)			
	M N	SD %	M N	SD %		
Beck Hopelessness Scale	4.10	3.19	3.66	2.88	1.09	.27
Fear Government	2.55	1.28	2.65	1.28	0.66	.51
Health Belief Model						
Perceived susceptibility	3.03	1.10	2.64	1.07	3.08	.002
Perceived treatment efficacy/severity	4.00	0.89	3.75	1.04	2.40	.02
Personal efficacy	2.65	1.28	2.60	1.31	3.32	.75
Theory Reasoned Action/ Planned Behavior						
Intentions ( <i>n</i>  %  $\chi^2$ )	157	49	20	20.4	25.2	.00
Personal health	5.77	0.87	5.66	1.01	1.02	.31
Social consequences	2.29	0.97	2.15	0.91	1.23	.22
Personal relationships	1.98	0.96	1.91	0.95	0.66	.51

### *Multivariate Analyses*

In addition to randomization to testing method (i.e., traditional counseling and testing & consumer-controlled testing), demographic, health status, HIV sexual and drug risk, and theoretical variables that were significantly related to HIV testing in the bivariate analyses were retained for multivariate logistic regression analyses. Initially, hierarchical stepwise logistic regression was used to build a model by entering the following blocks of variables; (1) demographics, (2) health status, (3) HIV risk, (4) theoretical, and (5) testing method. The rationale was to determine if testing method was significantly associated with HIV testing after accounting for the variables included in the prior steps.

Omnibus statistics from the hierarchical logistic regression are presented in Table 24. Of the demographic variables shown to be related to HIV testing in the bivariate analyses, only study site and a previous history of homelessness were related to testing in the multivariate model. Using the Cox/Snell  $R^2$ , these two variables accounted for approximately 12% of the variance in HIV testing. No health status variables entered in the second block were significantly related to HIV testing. Of the HIV risk variables entered in block three, both the RAB drug risk score and a previous history of a STD were related to HIV testing, accounting for approximately 3% of additional variance in HIV testing beyond that of the demographic variables. When theoretical variables were entered in the model, recent intentions to test for HIV and the perception of treatment efficacy/disease severity accounted for an additional 3.8% of explained variance in HIV testing. Finally, entering testing method in the last step of the model accounted for an additional 2.3% of explained variance in HIV testing. In total, the model accounted for 21% of the variance in HIV testing as indicated by the Cox/Snell  $R^2$ .

Table 24

Hierarchical Logistic Regression of HIV Testing: Reduced Model Omnibus Statistics

Variable/Block	Model $X^2$	-2LL	$\Delta$ -2LL	Cox/Snell $R^2$	$p_{step}$
<b>Intercept Only</b>		412.2			
<b>Block 1: Demographic Variables</b>					
Study Site	41.1	370.7	41.5	.105	.000
Ever Homeless	49.1	363.2	7.5	.123	.006
<b>Block 2: Health Status Variables -</b>					
No variables entered	-	-	-	-	-
<b>Block 3: HIV Risk Variables</b>					
RAB Drug Risk	55.3	356.9	6.3	.138	.012
Ever STD	60.8	352.2	4.7	.149	.030
<b>Block 4: Theoretical Variables</b>					
Intention to Test	72.8	339.3	12.9	.178	.000
Perceived Severity/Treatment Efficacy	77.1	335.1	4.2	.187	.041
<b>Block 5: Testing Method</b>					
Consumer-Controlled Testing	88.0	324.2	10.9	.210	.001

The adjusted odds ratios of the independent variables associated with HIV testing in the multivariate model indicate that participants in the syringe exchange program were approximately four times more likely than those from the methadone program to be tested, whereas those from the detoxification program were about half as likely as participants from the methadone program to be tested (Table 25). Participants who reported a history of homeless were almost twice as likely as those who did not, to report being tested at follow-up. With regard to HIV risk, an increase of one standard deviation in the RAB drug risk score was associated with a 1.07 increase in the odds of testing while in the study. Participants who reported having had a STD over their lifetime were twice as likely as those who did not to be tested. With regard to theoretical variables, a one standard deviation increase in perceived



treatment efficacy was associated with a 1.35 increase in the odds of testing, and participants who reported a recent intention to test for HIV were almost 3 times more likely to test than participants who did not. Finally, participants randomized to CCT were 2.61 times more likely to test than those randomized to traditional counseling and testing.

Table 25

Hierarchical Logistic Regression HIV Testing: Odds Ratios and Confidence Intervals

Variable/Block	<i>Unadjusted Odds Ratio</i>	<i>95% CI</i>	<i>Adjusted Odds Ratio</i>	<i>95% CI</i>	
<b>Block 1: Demographic Variables</b>					
Study Site					
Kensington	0.83	0.51 – 1.36	0.52	0.29-0.93	
Prevention Point	11.62	4.06 – 33.5	4.40	1.49-13.7	
ACT (reference)	-	-	-	-	
Ever Homeless					
No	-	-	-	-	Yes
2.89	1.76 - 4.73		1.87	1.02-3.42	
<b>Block 2: Health Status Variables</b>					
No variables entered	-	-	-	-	
<b>Block 3: HIV Risk Variables</b>					
RAB Drug Risk	1.13	1.07 – 1.19	1.07	1.01-1.14	
Ever STD					
No (reference)	-	-	-	-	Yes
1.77	1.09 – 2.88		2.01	1.13-3.59	
<b>Block 4: Theoretical Variables</b>					
Perceived Severity/Treatment Efficacy	1.32	1.04 – 1.67	1.35	1.02 -1.78	
Intention to test in past 30 days					
No (reference)	-	-	-	-	
Yes	3.78	2.21 – 6.47	2.97	1.58-5.59	
<b>Block 5: Testing Method</b>					
Traditional Testing (reference)	-	-	-	-	
Consumer-Controlled Testing	2.23	1.39 – 3.57	2.61	1.49-4.56	

### *Moderators of HIV Testing*

While the initial multivariate model is informative with regard to the “main effects” related to HIV testing among participants in this study, it is also helpful to evaluate the potential moderators of testing. Conceptually, moderators specify on whom and under what conditions another variable will operate to produce an outcome (Kraemer et al., 2001). Potential moderators of the relationship between testing type and HIV testing in this study suggested by the initial multivariate analysis included study site, a history of homelessness, having had a STD, and reporting a recent intention to test for HIV. Of these variables, additional analyses indicated that study site and a history of homelessness moderated the relationship between randomization to study arm (testing method) and HIV testing in this study.

In the context of this study, an important question is whether HIV testing differed across study site as a function of testing method? That is, does testing method increase the likelihood of testing in some drug treatment contexts, but not others? To evaluate this question a testing method by study site interaction term was added to the multivariate model and this parameter was found to be significantly related to HIV testing (Wald = 7.33,  $p \leq .026$ ). A plot of the site by testing method interaction is presented in Figure 2.

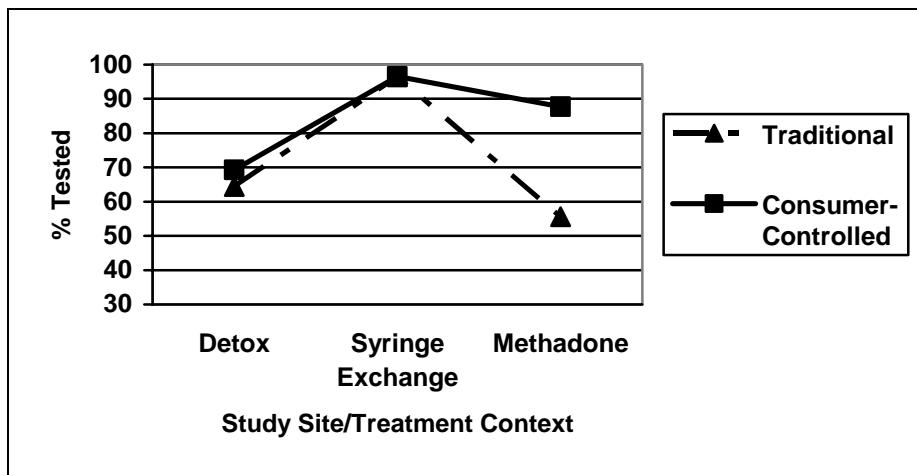


Figure 2. HIV Testing by Study Site and Testing Method

Figure 2 confirms that participants from the syringe exchange program were more likely to be tested than participants from the other sites/drug treatment contexts. However, syringe exchange participants were more likely to test regardless of testing method, as were participants from the detoxification hospital. Thus, CCT was associated with increased testing only among participants in the methadone program ( $X^2=19.2, p \leq .0001$ ).

Another question as to a potential moderator suggested by the results of the initial multivariate analysis, is whether HIV testing varied as a function of both testing method and a history of homelessness? Identifying such an effect would potentially provided additional information as to the context and for whom CCT might be most effective. This term approached significance in the multivariate model (Wald = 3.82,  $p \leq .051$ ) and given the limited sample size in this study is worthy of consideration. A plot of the history of homelessness by testing method interaction is presented in Figure 3.

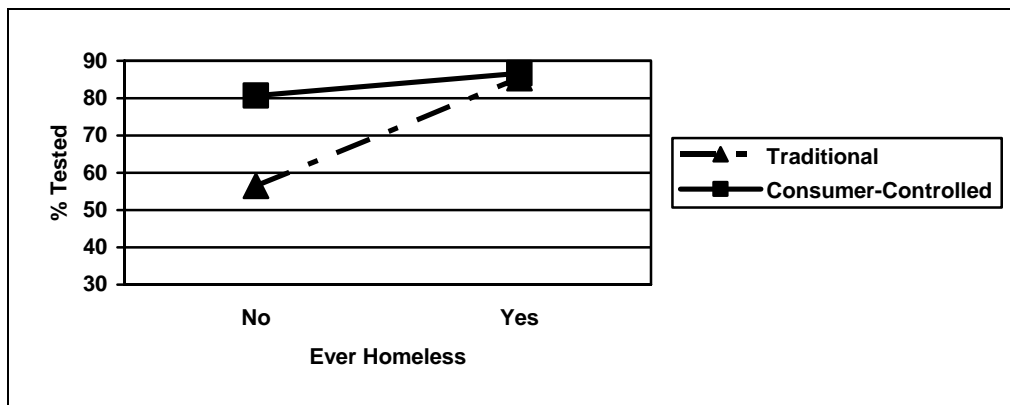


Figure 3. HIV Testing by History of Homelessness and Testing Method

Figure 3 illustrates that persons who did not report a history of homeless and were randomized to the CCT group were more likely than those randomized to TCT, to report testing for HIV while in the study ( $X^2=15.2, p < .0001$ ). Participants who did report a history of homelessness were equally likely to report testing for HIV in the study regardless of testing method.

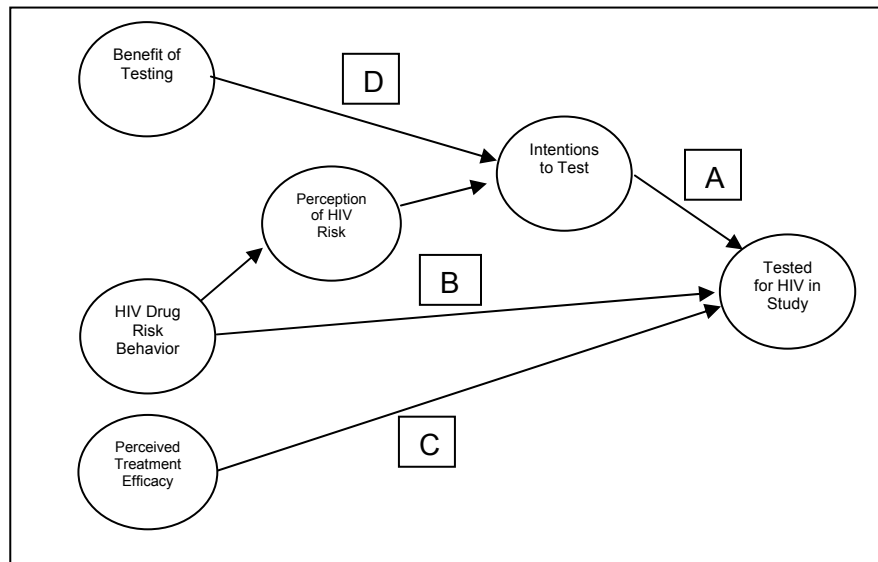
#### *Mediators of Testing Method and HIV Testing*

While the hierarchical logistic regression analysis of HIV testing presented in Tables 24/25 is informative with regard to estimating the effect of testing method beyond that of demographic and theoretical variables, it does not address the potential mediators associated with HIV testing. Conceptually, a mediating variable is one that explains how or why another variable affects an outcome (Kraemer et al., 2001). Similarly, in clinical trials mediators identify why and how treatments have effects (Kraemer, 2002). For example, variables that may not be directly related to HIV testing in this study, but may indirectly influence testing through their

associations with variables such as intentions to test, may also provide insight as to strategies for increasing HIV testing among persons at significant risk of HIV.

Because behavioral intentions have been implicated as the immediate precursor to behavior (Ajzen, 1985; Fishbein et al., 1975), and were directly related to HIV testing in this study, additional analyses were conducted in order to evaluate a broader, potentially more comprehensive model of HIV testing that included the correlates of behavioral intentions. Including such variables would allow for analyses assessing behavioral intentions as a potential mediator associated with HIV testing. Based upon the Health Belief Model and the Theories of Reasoned Action/Planned Behavior, intentions to test were regressed on drug-related risk for HIV, as well as perceptions of personal risk of HIV infection, treatment efficacy, personal efficacy to cope with HIV diagnosis, normative attitudes toward testing, benefit of regular testing, potential stigma, and negative reactions from others if HIV positive. After controlling for study site, of these variables, perception of HIV risk (OR = 1.23, 95% CI= 1.02 - 1.48) and perceived benefit of regular testing (OR = 1.78, 95% CI= 1.37 - 2.24) were found to be related to a recent intention to test for HIV.

When considering perception of HIV risk and perceived benefit of regular testing along with the variables show to be related to HIV testing in the hierarchical logistic model, at least one conceptual model of HIV testing can be hypothesized. This potential conceptual model is presented in Figure 4



*Figure 4. Conceptual Model of HIV Testing*

This model illustrates the relationships observed in the initial hierarchical logistic regression analysis. For example, it reflects the observed effects of intentions to test (A), drug risk (B), and perceived treatment efficacy on HIV testing (C). It also incorporates the results of the logistic regression analysis of recent intentions to test by including an effect of the perceived benefit of regular HIV testing on intentions to test (D). Furthermore, it suggests that perception of HIV risk potentially mediates the relationship between HIV drug risk behavior and intentions to test. This relationship implies that HIV drug risk influences intentions to test via perception of HIV risk. The model also suggests that intentions to test might mediate the relationships between the perceived benefit of testing and perceptions of HIV risk on HIV testing.

Because the dependent variables suggested by this conceptual model (i.e., testing for HIV in the study and intentions to test) are dichotomous rather than continuous, it is not possible to estimate the direct and indirect effects of the model variables on HIV testing as might be done

using path analysis or structural equation modeling (Cohen & Cohen, 1983). However, tests for mediation using logistic regression analysis evaluating the dominance and codominance of variables as they relate to each other and the dependent variable can be conducted on each potential triad of variables that may include a mediating variable (Kraemer, Stice, Kazdin, Offord, & Kupfer, 2001; Baron & Kenny, 1986). Given the analytic constraints associated with the dichotomous variables, the potential mediating relationships among variables in the conceptual model were identified and tested individually. These results are presented in Figure 5.

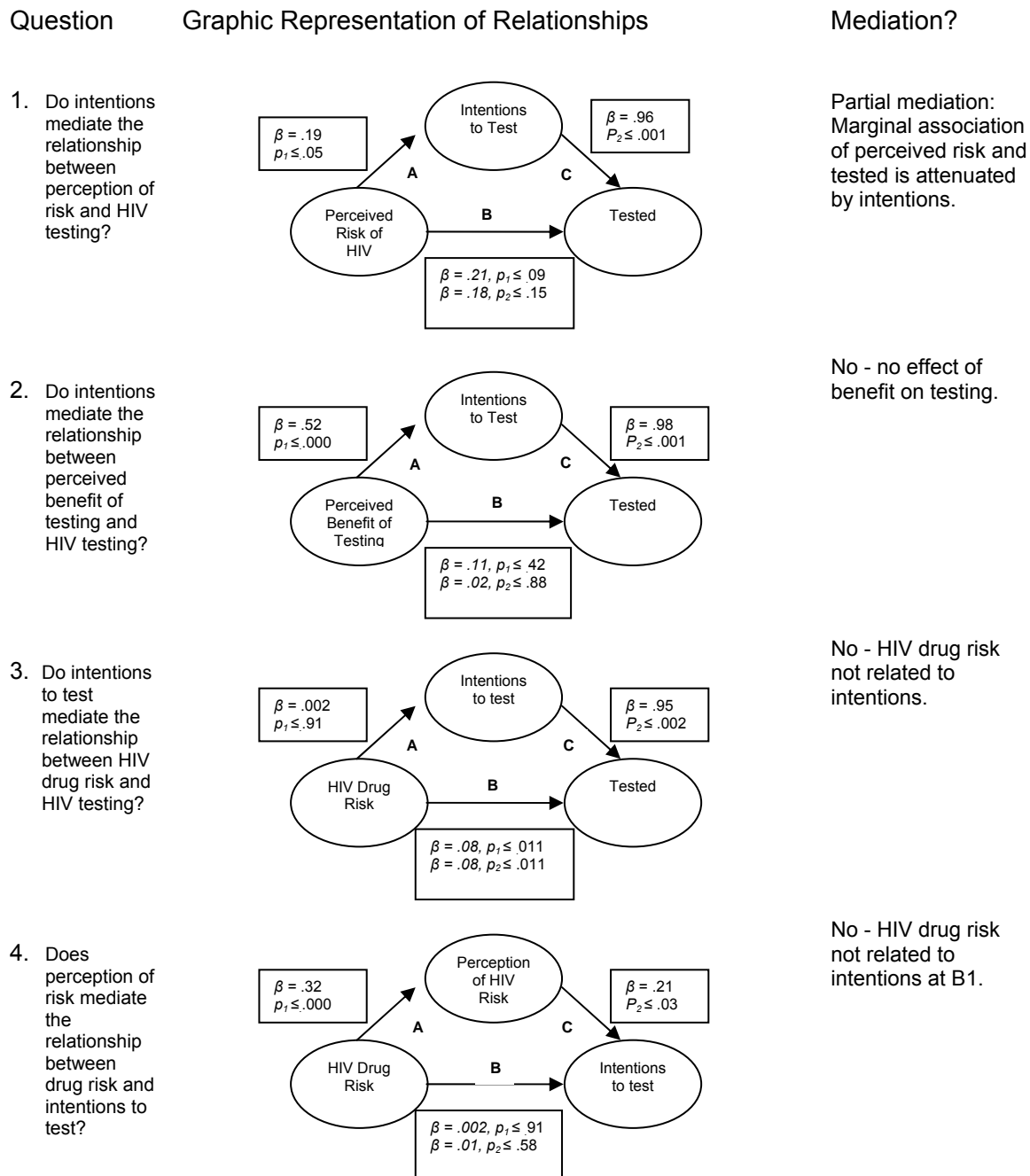


Figure 5. Results of Mediation Analyses



These results indicate that intentions to test partially mediate the relationship between perceived risk of HIV infection and testing in the study. Other potential mediators suggested by the conceptual model in Figure 4 were not confirmed in these analyses, suggesting that the relationships of the independent variables and the potential mediator were “overlapping factors” associated with a dependent variable, but not mediating factors (Kraemer et al., 2001).

#### *Satisfaction with HIV Counseling and Testing*

Participants were asked to rate the degree of satisfaction with their HIV counseling and testing experience in the context of this study across 16 satisfaction variables. In general, participants in the CCT arm rated their testing experience more highly than those in the TCT arm (Table 26). Pre- and post-test counseling, location and quality of testing, information provided during counseling, cost of services, and time spent waiting for results were all rated more favorable by CCT participants than TCT participants. No differences between groups were noted with regard to the staff attitudes and concerns toward drug users, the confidential nature of testing, referrals, or knowledge and professionalism of the staff.

Table 26

## Satisfaction with HIV Counseling and Testing

Satisfaction Variable	Testing Method				t	p
	CCT		Traditional			
	X	SD	X	SD		
Location of testing	4.71	.76	4.35	.96	3.57	0.000
The quality of testing	4.66	.75	4.26	.97	4.03	0.000
Information provided	4.62	.77	4.19	1.15	3.78	0.000
Time spent	4.48	.97	3.99	1.25	3.71	0.000
Staff attitude toward drug users	4.51	.86	4.30	1.17	1.59	0.113
Staffs concern and care about you	4.38	1.00	4.18	1.16	1.38	0.168
Cost of services	4.88	.48	4.66	.68	3.08	0.002
Pre-test counseling	4.49	.85	4.14	1.04	3.04	0.003
Post-test counseling	4.40	1.05	3.96	1.30	2.57	0.011
Confidential nature of testing	4.77	.64	4.65	.85	1.33	0.183
Time spent with you	4.47	.98	4.22	1.08	1.84	0.680
Referrals provided to you	3.77	1.63	3.63	1.51	0.48	0.630
Time spent waiting for results	4.33	.99	3.77	1.33	3.87	0.000
Blood draw	4.11	1.16	4.22	1.12	-0.81	0.420
Knowledge of staff	4.41	.99	4.31	1.11	0.77	0.440
Professionalism of staff	4.58	.88	4.35	1.14	1.78	0.076

## CHAPTER 4

### DISCUSSION

In this study, marginalized individuals with few economic resources and a recent history of drug use behavior placing them at-risk of HIV infection were targeted for an evaluation study of different HIV testing methods. The primary objective of the study was to determine if testing method (i.e., consumer-controlled testing versus traditional HIV counseling and testing) was associated with different rates of testing between participants randomized to the two methods of HIV testing. The secondary objectives of the study were to determine for whom and under what conditions testing method was related to HIV testing and also to identify theoretical factors related to HIV testing. Because the social, demographic, and HIV risk-related factors among drug users can vary greatly across prevention and treatment contexts, three study sites serving injecting drug users across a continuum of drug treatment participated in the study; out-of-treatment drug users (syringe exchange program), methadone maintenance (i.e., substitution therapy) patients, and individuals in a hospital-based drug detoxification program.

#### *Factors Related to Study Enrollment*

In public health evaluation studies that employ convenience sampling it is useful to understand the characteristics of those who enroll in a study and those who do not, for the purposes of prevention research and programming planning. In this study, differences were observed between individuals who enrolled in the study and those who did not with regard to demographic, HIV risk behavior, and theoretical variables. Multivariate analyses indicated that Blacks/African Americans were more likely to enroll than were other ethnic groups. Given that

HIV disproportionately affects the African American community (CDC, 2000; CDC, 2004) their willingness to participate in public health studies such as this is encouraging, especially when considering reports that African Americans are less likely to participate in research studies in a variety of contexts (Guinan, 1993; Sengupta et al., 2000; Fullilove, 2004). However, the multivariate analyses also indicated that individuals who were more likely to be marginalized, as indicated by a lack of employment or a lack of involvement in drug treatment, were less likely than more “stable” individuals to participate in the study. This suggests that those who were most at-risk of HIV infection were less likely to participate in this study that could have provided them with an opportunity to learn their HIV serostatus, and if seropositive, to have been referred for medical care. That these marginalized individuals were least likely to participate in the study underscores the need to develop appropriate methods to reach and engage this population. Furthermore, this phenomena is consistent with reports in the literature that involvement in drug treatment may facilitate HIV prevention efforts (Metzger & Navaline, 2003).

However, while individuals potentially at the greatest risk of HIV infection declined to participate in the study, a significant majority of those who did enroll reported recent injection drug use and sharing of injecting equipment, indicating that those who enrolled were at substantial risk of HIV infection. Furthermore, individuals who did choose to participate in the study had few economic resources, little education, were unlikely to live in their own home, and were likely to be on welfare. Thus, both the HIV risk behavior reported by study participants and their lack of economic resources suggest that this study population was both marginalized and at significant risk of HIV infection.

### *Randomization*

The design used in this study was a randomized prospective field experiment. Randomized designs are considered to be optimal for evaluating the effectiveness of

interventions because they strengthen internal validity by establishing groups of approximately equal composition (Cook, 2002; Berk, 1985; Cook & Campbell, 1979). In this study, participants were randomized to either TCT or CCT. The randomization assessment indicated that the randomization did result in two nearly identical groups. That is, demographic characteristics, HIV risk behavior, and most theoretical variables were equivalent across groups. One difference between participants randomized to TCT and CCT was that those randomized to TCT were more likely to perceive that testing might negatively impact personal relationships. This difference could have resulted in fewer individuals in the TCT group being tested for fear that testing would adversely impact personal relationships. However, even when controlling for perceived negative impact on social relationships, participants randomized to the CCT arm of the study were more likely to be tested than those randomized to TCT.

### *Study Attrition*

Of concern in longitudinal randomized studies is the potential for differential attrition across the arms of a study. In this study differential attrition between TCT and CCT arms could have resulted in different testing outcomes between the two study arms when in fact no real difference existed. However, there was not differential attrition between treatment arms in this study. Multivariate analyses indicated that participants enrolled from the detoxification program were more likely to be lost to follow-up than were participants from the methadone maintenance or syringe exchange programs. A differential loss to follow-up among study sites could have biased testing across sites, however, because there was not differential attrition by treatment arm, such a bias would not be expected to disproportionately influence the number of individuals tested in the TCT and CCT arms. Finally, as in the evaluation of study enrollment, participants at greatest drug-related risk of HIV infection as indicated by the RAB drug risk score, were also somewhat more likely to be lost to follow-up. However, those that were

retained reported substantial drug-related risk behavior with two-thirds reporting injecting drugs in the past six months.

### *HIV Testing Outcomes*

Consumer-controlled testing (CCT) in this study was associated with increased HIV testing relative to traditional counseling and testing (TCT). Furthermore, participants randomized to CCT were more satisfied with this testing methodology than were those randomized to TCT. However, individuals in the CCT arm of the study were no more likely than those in the TCT arm to obtain their HIV test results. Nonetheless, consistent with recent HIV prevention initiatives stressing the importance of individuals learning their HIV status (De Cock, Marum, & Mbori-Ngacha, 2003; Janssen et al., 2001) these data suggest that CCT could result in a net increase in the number of individuals at significant risk of HIV who learn their HIV status beyond that of traditional clinic- and provider-based HIV testing.

However, the effect of CCT on increased HIV testing was only observed within one of the three HIV drug treatment environments, the methadone program, and among persons who did not report a history of homelessness. These results suggest that HIV testing options beyond traditional HIV counseling and testing may appeal to some individuals, resulting in an increase in HIV testing, but may not appeal to others. It is likely that the availability of multiple testing options offered outside of medical settings would have broader appeal to different groups at-risk of infection and would result in increased HIV testing, diagnosis, and treatment.

While new testing technologies are now becoming available in the United States that provide HIV test results within minutes (CDC, 2003), these tests are currently only available in clinic- and service-based settings. The reduced waiting time for one's test result offered by these rapid tests may eliminate one potential barrier to HIV testing, however, nonclinic-based options that would allow an individual to self-test and learn their result in private, without the aid

of a clinician, may ameliorate additional barriers to testing. Perhaps such an option would have been more appealing to those individuals at-risk of HIV infection that chose not to enroll in this study and reported income from sources likely to be associated with illegal activities?

As the empowerment perspective suggests, the availability of an alternative testing method that allows individuals to control their own destiny and decision making, may increase volitional control and reduce barriers to testing. CCT is consistent with empowerment theory because it offers the opportunity for self-determination. The added ability to learn one's own test result without the need for clinician involvement might also further reduce barriers to testing, consistent with the self-determination aspect of empowerment theory. Such a self-testing model has been successful for other contexts, such as pregnancy testing. And while some may be concerned with isolated self-testers not having adequate social support and counseling should they find that they are HIV seropositive, participants were more satisfied with the phone counseling offered by the Home Access Health Corporation (the manufacture of the HIV home testing kit used in this study) than they were with traditional counseling. This indicates that such counseling strategies can be successfully delivered, however, further evaluation of such counseling methods for HIV seropositive individuals would be advisable.

#### *Theoretical Correlates to HIV Testing*

Several of the theoretically oriented variables evaluated in this study were related to HIV testing and may help inform strategies to increase testing among individuals at-risk of HIV infection. Both the Theories of Reasoned Action and Planned Behavior assume that intentions are the immediate determinant of behavior (Ajzen, 1985; Fishbein et al., 1975). Consistent with these theories, an intention to test for HIV in the thirty days prior to study enrollment was related to HIV testing in the study.

The conceptual model of HIV testing proposed in Figure 4 includes two predictors of intentions identified in this study; the belief that HIV testing is important from the perspective on one's personal health care strategy, and one's personal perception of HIV risk. The implication is that if awareness as to the potential benefits of HIV testing could be increased among persons at-risk of HIV infection, intentions to test, and subsequent testing might increase as well. Thus emphasizing testing as a personal health strategy by stressing that testing may reduce anxiety regarding one's HIV status, facilitate health-protective behavior, promote early management of HIV infection, and result in referrals to social and peer support if needed may help to encourage intentions to test. Caution is warranted however. Serial HIV negative antibody test results in the context of ongoing risk behavior could reduce anxiety about HIV risk behavior and facilitate ongoing or perpetuate increases in the frequency of such behavior (MacKellar et al., 2002). Risk reduction programs must be able to address the possibility of undue optimism related to repeated HIV negative test results in the context of ongoing HIV risk behavior.

Perception of HIV risk was also related to intentions to test with an increase in perception of risk being associated with an increase in perception of HIV risk. While actual risk behavior in this study was positively associated with perception of risk, individuals tend to have an optimistic bias that they are not at risk of a disease when in fact they are (Weinstein, 1982; Weinstein, 1987). Thus, health education efforts that address HIV transmission dynamics and also personalize this information for their constituents so as to reduce optimistic bias regarding actual risk might also result in increased intentions to test for HIV. The results of the analyses of intentions to test as a mediator of perceived risk and HIV testing (Figure 5) suggest that increasing perception of risk would have both a direct and an indirect effect on HIV testing.

Conceptually related to the belief that testing is beneficial from an individual health perspective, is the perception that the available treatments for HIV are highly effective. The



perception of treatment efficacy had a direct effect on HIV testing with those perceiving the available treatments to be efficacious being more likely to test than those who perceived treatments to be less efficacious or otherwise undesirable. The implication is that if awareness of treatment efficacy is increased among individuals at-risk of HIV infection, testing might increase because of the perception that effective therapeutic agents exist. However, a cautionary note is worthy of mention. That is, such perceptions of effective therapies have been widely implicated as a precursor to increasing risk behavior and HIV/STD infection rates among MSM (Centers for Disease Control and Prevention, 1999b; Crepaz, Hart, & Marks, 2004; Fox et al., 2001; Mansergh, 2002; Scheer et al., 2001). Thus, a balanced presentation of the efficacy of therapeutic agents along with some presentation of their disadvantages would be warranted.

This study found that CCT increased HIV testing relative to TCT in a subgroup of individuals at high-risk of HIV infection due to injecting drug use and the sharing of injecting equipment. Consistent with empowerment theory, the data indicated that providing HIV testing options that allowed marginalized individuals with few resources to control their own destiny resulted in health-enhancing decisions and behavior. Also consistent with empowerment theory was that the observed outcomes of testing method differed by context and population (Zimmerman, 2000). In addition to testing method, theoretical variables also suggested strategies for enhancing HIV testing among drug users such as emphasizing the specific benefits of testing, as well as the efficacy of available treatments for HIV, although such strategies must be pursued with caution.

CCT technology as indicated by these study data potentially ameliorated barriers to testing that resulted in increased testing among some study participants. However, the method of sample collection associated with this technology (finger stick with a lance) is difficult and aversive for some individuals. The next logical step for further reducing barriers to HIV testing among individuals at risk of HIV infection would be to incorporate oral fluid testing in home HIV

test kits, and to further eliminate the need for a third party to provide results by allowing for a rapid HIV test result similar to that of home pregnancy testing. This method could make counseling available on an as needed basis, delivered by telephone, and contingent upon the volitional control of the testing consumer.

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## Appendix A

## Theoretically Derived Items and Constructs

Theory	Item
<b>Health Belief Model</b>	
Perceived Susceptibility	<ol style="list-style-type: none"> <li>1. There is little chance that I could be infected with HIV.</li> <li>2. My behavior places me at risk of getting HIV.</li> <li>3. My sexual behavior is risky in terms of HIV.</li> <li>4. I am more likely to die from violence than I am to die from AIDS.</li> </ol>
Treatment Effectiveness	<ol style="list-style-type: none"> <li>1. There is nothing you can do to treat HIV so why get tested?</li> <li>2. Effective drugs are now available for people infected with HIV.</li> <li>3. You can live a long time if you're infected with HIV.</li> <li>4. A positive HIV test means that you don't have long to live.</li> </ol>
Personal Efficacy	<ol style="list-style-type: none"> <li>1. I wouldn't be able to cope well if I tested HIV positive.</li> <li>2. If I tested HIV positive, I wouldn't be able to handle it emotionally.</li> <li>3. My life would fall apart if I tested HIV positive.</li> <li>4. If I were HIV positive, there is a lot I could do to help myself.</li> <li>5. If I were HIV positive, I could cope well.</li> </ol>
Medical Care	<ol style="list-style-type: none"> <li>1. I am able to get medical care when I need it.</li> <li>2. If I needed hospital care, I could get admitted without any trouble</li> <li>3. Sometimes I go without medical care because it is too expensive.</li> </ol>

<b>Theories of Reasoned Action/Planned Behavior</b>	
Intentions to get tested	<ol style="list-style-type: none"> <li>1. In the past 30 days, had you made a definite decision to get tested for HIV?</li> </ol>
Perception of Subjective Norms	<ol style="list-style-type: none"> <li>1. My close friends think that getting tested for HIV is important.</li> <li>2. Most people I know would not get tested for HIV.</li> <li>3. My primary partner has been tested for HIV.</li> <li>4. My sex partner(s) think that it is important to get tested for HIV.</li> <li>5. Most of the people I hang out with have been tested for HIV.</li> </ol>
Personal Health	<ol style="list-style-type: none"> <li>1. Getting tested for HIV helps me to feel better about my health</li> <li>2. I would worry less about my health if I got tested for HIV.</li> <li>3. By getting tested for HIV I am doing something good for my health.</li> <li>4. HIV testing is an important part of my regular health care.</li> </ol>
Social Consequences - Stigmatization	<ol style="list-style-type: none"> <li>1. If I get tested for HIV people might think that I have AIDS.</li> <li>2. People in my life would leave me if I told them I have HIV.</li> <li>3. If I get tested for HIV people might think that I use drugs.</li> <li>4. If I get tested for HIV people might think that I am gay.</li> </ol>
Personal Relationships	<ol style="list-style-type: none"> <li>1. I fear that my sex partner will leave me if I get tested for HIV</li> <li>2. I fear that I will loose my friends if I get tested for HIV.</li> <li>3. I fear that my sex partner will leave me if I test HIV positive.</li> </ol>
<b>Distrust of Government</b>	

	<ol style="list-style-type: none"><li>1. I'm not sure that the federal government can be trusted.</li><li>2. HIV is a man-made virus that was created to get rid of certain groups of people.</li><li>3. Sometimes I think the government is using AIDS to kill off people who are not wanted by society.</li><li>4. There is a cure for AIDS but the government is keeping it from people.</li></ol>
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