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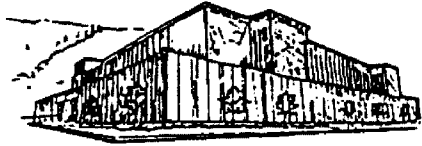
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**AN OUTCOME EVALUATION OF AN OUTREACH PROGRAM FOR
INJECTION DRUG USERS**

By

Corey Renee Campbell

Bachelors of Science Montana Tech of The University of Montana, 2002

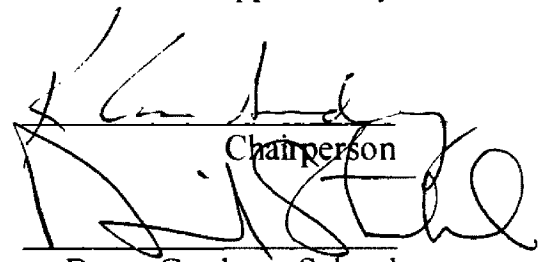
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Masters of Science

The University of Montana

August 2004

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An Outcome Evaluation Of An Outreach Program For Injection Drug

Thesis Chair: K. Ann Sondag

A study was conducted to examine the effectiveness of an intervention designed to increase HIV and Hepatitis C preventative behaviors among injection drug users (IDUs) residing in chemical dependency centers. The intervention was developed based on the Informational-Motivation-Behavioral Skills Model (IMB). Seventy IDUs participated in the study. Approximately one-half of the participants received a one-hour HIV and Hepatitis C prevention intervention with an indigenous outreach worker, while the other half did not receive the intervention. A self-report survey was developed and was designed to measure three determinants of HIV preventive behaviors: 1) participants' knowledge of HIV and Hepatitis C prevention, 2) participants' motivation to engage in preventive behavior, and 3) participants' intent and perceptions of efficacy to perform the behavioral skills needed to engage in preventative behaviors. The survey was administered prior to and two weeks after the intervention to evaluate the effectiveness of the intervention. An ANCOVA revealed significant differences ($F=.67, p<.05$) on posttest scores between the two groups. In addition, the intervention group demonstrated important net gains on their average survey scores from pretest to posttest in the information, motivation, and behavioral components, while the control group did not. These findings support the hypothesis that an HIV and Hepatitis C prevention outreach program can be effective in increasing IDUs' knowledge, motivation, and perceived efficacy to perform preventative HIV and Hepatitis C behaviors. This study also illuminates the need for theoretical based interventions that address HIV and Hepatitis C risk behaviors among IDUs.

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CHAPTER I

Introduction to the Study

Statement of the Problem

Human immunodeficiency virus (HIV), the cause of AIDS, is the defining medical and public health issue of our generation and ranks among the greatest infectious disease scourges in history (Fauci, 1999). AIDS, acquired immunodeficiency syndrome, was first reported in the United States in 1981 and has since become a major worldwide epidemic. Since 1981, more than 886,000 cases of AIDS have been reported in the United States and as many as 950,000 Americans may be infected with HIV, one-quarter of whom are unaware of their infection (NIAID, 2003). Equally alarming is the number of Americans infected with the Hepatitis C virus. The Centers for Disease Control reports an estimated 2.7 million Americans are chronically infected with Hepatitis C (CDC, 2002b). An estimated 25,000 people are newly infected with the Hepatitis C virus each year, causing approximately 8,000-10,000 liver disease deaths among those infected (CDC, 2002b).

Injection Drug Use (IDU) is a significant risk factor for AIDS (CDC, 1982) and the single most important risk factor for Hepatitis C infection (CDC, 1998; Garfien et al., 1996). One third, approximately 240,000 of the AIDS cases reported to date, can be attributed to injection drug use (CDC, 2002) while approximately 50 to 95 percent of individuals infected with Hepatitis C report a link to injection drug usage (Garfien et al., 1996). IDUs can introduce HIV and Hepatitis C into their drug community where, through the sharing of needles and injection equipment, it has the ability to spread rapidly

and infect large proportions of individuals who inject and share drugs (Habib, 2003). As a result of the high incidence of HIV and Hepatitis C infection, effective preventative interventions to assist IDUs adopt risk reduction behaviors are needed.

There are three common approaches to HIV and Hepatitis C prevention among IDUs (Watters and Guydisk, 1994). The first of these involves punishing IDUs for the illegal use of illicit drugs and using the criminal justice system to remove IDUs from society (Morse et al., 1998). The second major approach involves treating drug use as an illness and using abstinence based treatment approaches through long-term hospitalization, methadone maintenance programs, outpatient, and self help groups (Watters and Guydisk, 1994). The third approach, harm reduction, suggests it is not always necessary to stop the use of illicit drugs but rather reduce the risk of exposure to disease by using harm-reduction methods to reduce the chance of HIV infection among IDUs (Morse, et.al., 1998).

The HIV and Hepatitis C prevention outreach program that will be evaluated in this study, *Taking it to the Population*, is based on basic harm reduction principles that aim to reduce rather than completely eliminate IDUs' risk behaviors (Des Jarlais et al., 1993). In addition, this intervention was developed utilizing the principles of the Informational, Motivational Behavioral Skills (IMB) model. The model, originally developed in response to the HIV epidemic, has been used for understanding and promoting various health behaviors. (Fisher and Fisher's study as cited in (Fisher and Fisher, in press)). According to the IMB model, HIV prevention information, motivation,

and behavioral skills are the three determinants of HIV preventative behavior (Fisher et al., 2002). The likelihood that individuals will initiate and maintain patterns of preventative behavior depends on the extent to which individuals are well informed, motivated to act, and possess the behavioral skills to act effectively (Fisher and Fisher, 2002). Thus, *Taking it to the Population* incorporates information, motivational strategies, and behavioral skills into the program to enhance the likelihood of positive behavioral change. HIV and Hepatitis C prevention outreach programs, such as *Taking it to the Population*, have been used as HIV and Hepatitis C prevention strategies for several years in Montana yet have never been evaluated. In order to fully understand how to best assist IDUs to decrease their risk for HIV and Hepatitis C, such intervention programs must be evaluated to determine if they meet their objectives and ultimately decrease IDUs' HIV and Hepatitis C risks.

Purpose of the Study

The purpose of this study is to examine the effectiveness of an intervention designed to increase HIV and Hepatitis C preventative behaviors among injection drug users (IDUs) in chemical dependency centers.

Hypothesis

There will be significant increases on IDUs' average scores between the intervention and control groups from pretest to posttest scores on the HIV and Hepatitis Prevention Survey.

Delimitations

- 1. Participants will be delimited to IDUs attending the HIV and Hepatitis C prevention outreach program in Montana.**
- 2. Participants in this study will be volunteers.**
- 3. Data will be collected using surveys.**
- 4. Data will be restricted to participants' self-reports.**

Limitations

- 1. Accuracy of data is dependent upon the participants' willingness and ability to answer honestly and accurately.**
- 2. Accuracy is dependent upon participants' ability to understand the survey statements.**
- 3. Responses may be dependent to social desirability.**

Definition of Terms

AIDS - Acquired immunodeficiency syndrome applies to the most advanced stages of HIV infection. The CDC defines AIDS as the presence of at least one of several opportunistic infections or the presence of fewer than 200 CD4 cells/mm³ in an HIV positive individual (AIDS Foundation, 1997).

COOKER – A container used to dissolve drugs in water and to heat drug solutions (NIDA, 2000).

COTTON – Used to filter out particles that could block the needle (NIDA, 2000).

HARM REDUCTION - An intervention approach that suggests it is not always necessary to stop the use of illicit drugs but rather reduce the risk of exposure to disease by using methods to reduce the chance of HIV infection among IDUs (Morse et al., 1998)

HEPATITIS C (HCV, formerly NON-A, NON-B HEPATITIS) - A contagious viral disease that causes inflammation of the liver (AIDS Foundation, 1997).

HEPATITIS C/CO-INFECTION WITH HIV- Patients infected with HIV are also infected with the Hepatitis C virus (AIDSInfo, 2003).

HIGH RISK SEX -Unprotected anal, vaginal, or oral sex; multiple partners; and lack of treatment of sexually transmitted diseases (STDs) (Strathdee, et al., 2001).

HIGHLY ACTIVE ANTIRETROVIRAL THERAPY (HAART) - Treatment regimens recommended to aggressively suppress viral replication and progress of HIV disease (AIDS info, 2003).

HUMAN IMMUNODEFICIENCY VIRUS (HIV)- A slow-acting retrovirus believed to be the sole or primary cause of AIDS. There are 2 known types: HIV-1 and HIV-2 (AIDS Foundation, 1997).

INJECTION DRUG USER (IDU) -A person who uses a drug that is administered with a needle and syringe (AIDS Foundation, 1997).

Importance of the Study

The results from the outcome evaluation of the HIV and Hepatitis C prevention HIV and Hepatitis C prevention outreach program, *Taking it to the Population*, will provide the Montana Department of Health and Human Services (DPHHS), as well as other health organizations, with valuable information concerning HIV and Hepatitis C prevention outreach programs. This information can be used as a framework to design interventions that may reduce the incidence of HIV and Hepatitis C among IDUs.

CHAPTER II

Review of Literature

HIV/AIDS in The United States

More than 830,000 cases of AIDS have been reported in the United States since 1981 (NIAID, 2003). Through the 1980's the incidence of AIDS continually increased. However, with the introductions of antiviral drugs from the mid-1990s through 2001 the incidence of reported AIDS cases decreased. Unfortunately in 2002, the incidence of AIDS increased 2%, compared with 2001. Since 1996, trends in AIDS cases have become less reflective of the underlying trends of HIV transmission due to the widespread use of Highly Active Antiretroviral Therapy also known as HAART. It is important recognize that even though the number of deaths among persons with AIDS continued to decline, the prevalence of HIV continues to increase (CDC, 2003a).

HIV is the virus that causes AIDS (CDC, 2002b). The virus can be transmitted in four different ways: through sexual contact with an infected person, through the sharing of needles or syringes among injection drug users (IDUs), through contact with infected blood, as well as from infected pregnant women who can pass HIV to their babies during pregnancy or delivery as well as through breast-feeding (NAIAD, 2003).

In the United States, injection drug use and sexual contact are the two main routes by which HIV is transmitted (AED, 2002). For injection drug users, transmission can occur through direct or indirect sharing of contaminated equipment. Additionally, the high-risk sexual behaviors usually associated with drug use also put IDUs at risk for HIV.

These risky sexual behaviors include unprotected anal, vaginal, and/or oral sex, as well as multiple sex partners, and lack of treatment of sexually transmitted diseases (STDs) (Strathdee, S.A., et al., 2001). To prevent transmission of HIV among IDUs, it is clear that efforts should focus on both safe injection practices and decreasing risky sexual behaviors (CDC, 1982).

HIV/AIDS in Montana

As of 2003 in Montana, 612 cases were reported that met the HIV/AIDS definition; 265 resulting in death. Men who have sex with men (MSM) account for 63 percent of the total HIV cases. Injection drug users (IDUs) account for 24 percent of total HIV/AIDS cases. This includes 13 percent reporting only IDU, as well as 11 percent reporting dual risk factors of MSM and IDU. In addition, 45 percent of heterosexual AIDS cases are linked to a partner who injected drugs. When this “indirect” link is considered, 29 percent of all reported cases are linked to IDU (Montana DPHHS, 2004). The remaining 23 percent of HIV/AIDS cases in Montana were acquired through transfusions related to hemophilia/coagulation disorder (2 percent), heterosexual contact (11 percent), transfusion with blood or blood products (2 percent), or cases that are currently under investigation (9 percent) (Montana DPPHS, 2004).

Hepatitis C in The United States

The Hepatitis C virus (HCV) infection is the most common chronic blood borne infection in the United States (CDC, 1998). The Centers for Disease Control reports an estimated 2.7 million Americans are chronically infected with Hepatitis C (CDC, 2002b).

Most people chronically infected with Hepatitis C do not know they are infected because they may not experience symptoms for 20-30 years after they are infected (CDC, 1998). An estimated 25,000 people are newly infected with the Hepatitis C virus each year, causing approximately 8,000-10,000 liver disease deaths among those infected (CDC, 2002b).

Like HIV, Hepatitis C can be transmitted through contact with infected blood or body fluids by ways of unprotected sex, injection drug use, through the birth process, as well as through blood transfusions. In addition, Hepatitis C is also transmitted through the sharing of infected toothbrushes or razor blades that contain blood or body fluids from an infected person (CDC, 2004).

Injection drug use is the single most important risk factor for Hepatitis C virus infection. Garfien and colleges (1998), estimate that 50 to 95 percent of IDUs are infected with Hepatitis C. Not only is Hepatitis C prevalent among IDUs but also it appears to be acquired relatively soon after drug injection is initiated. One study estimating the prevalence of blood-borne viral infections among illicit IDUs, reported that 50 to 80 percent of new IDUs became infected with Hepatitis C within 6 to 12 months of first injecting (Garfien et al., 1996).

Because HIV and Hepatitis C are both transmitted through exposure to infected blood or body fluid, coinfections of Hepatitis C and HIV are common (CDC, 2002c). In 2000, an estimated 240,000 persons were coinfecting with Hepatitis C and HIV. HIV and Hepatitis C coinfections account for approximately 30% of those individuals with HIV

infections (Sulkowski et al, 2000).

Hepatitis C in Montana

According to The Montana Department of Health and Human Services (DPHHS), 6464 persons have been reported to be Hepatitis C positive in Montana (L. Baus, personal communication, February 24, 2004). However, because most people chronically infected with Hepatitis C are not aware that they are infected (CDC, 1998), the Montana Department of Public Health and Human Services, Hepatitis C Division, estimates there are approximately 16,280 cases of Hepatitis C in Montana. This is an estimate based on National Hepatitis C data. Nationwide, approximately 16% of the population is Hepatitis C positive (L. Baus, personal communication, February 24, 2004).

Prevention of HIV and Hepatitis C in the United States

As previously mentioned, Injection Drug Use is a risk factor for AIDS (CDC, 1982) and Hepatitis C (Garfien et al., 1996). Injection Drug Users account for one third, approximately 240,000 of the AIDS cases reported to date (CDC, 2002a) and approximately 50 to 95 percent of individuals infected with Hepatitis C report a link to IDU (Garfien et al., 1996). IDUs who share injection equipment can introduce the viruses into their drug community where they have the ability to spread rapidly and infect large proportions of individuals who inject and share drugs (Habib, 2003). IDUs become infected and transmit the viruses to others in two, often interconnected, ways. The first is the sharing of blood contaminated syringes and injection paraphernalia such as water, cookers, and cottons. The second method of HIV and Hepatitis C transmission among

IDUs is high-risk sex, which can be defined as unprotected sex, sex with multiple partners, and/or failures to treat STDs (AED, 2002).

There are three common approaches to HIV and Hepatitis C prevention among IDUs (Watters and Guydisk, 1994). The first of these involves punishing IDUs for the illegal use of illicit drugs and using the criminal justice system to remove IDUs from society (Morse et al., 1998). In the late 1990's, approximately 83 percent of all state prisoners (837,300) and approximately 73 percent of all federal prisoners (64,000) reported past drug use. One third of state prisoners and one fifth of federal prisoners reported using drugs at the time they committed the offense for which they were in prison (CDC, 2001). The large numbers of drug users in the criminal justice system and their high risk of acquiring and transmitting HIV, STDs, and Hepatitis C, creates an urgent need for high quality prevention, treatment, and care services for incarcerated individuals. In addition, it is also crucial that inmates receive these prevention services after they are released. Without these services, inmates return to their communities and often revert to the behaviors that put them in prison. This increases the chances they will use drugs, commit crimes, spread or acquire disease, and return to prison or jail (CDC, 2001).

The second major approach to HIV and Hepatitis C prevention involves treating drug use as an illness and using abstinence based treatment approaches through long-term hospitalization, methadone maintenance programs, outpatient, and self help groups (Watters and Guydisk, 1994). The goal of this approach is to provide guidance and social support for eradicating drug use and is encouraged for IDUs who want to stop the use of

drugs but can't do so on their own (Morse et al., 1998). Abstinence-based programs are based on the idea that the cessation of all drug use and drug injection is the most effective strategy for risk reduction (Morse et al., 1998). Although abstinence based drug treatment is an effective method for helping many IDUs overcome drug addiction and reducing both needle and sex-related HIV risks (Des and Hubbard, 1999), some IDUs are not ready to discontinue drug use (NIDA, 2000). Further, if IDUs do manage to discontinue drug use, often times relapse occurs (Simpson and Marsh, 1986).

As a result, other prevention strategies, such as harm reduction, in addition to drug abuse treatment are needed for those who continue to use drugs and those who are prone to relapse (NIDA, 2000). The third HIV and Hepatitis C prevention approach, harm reduction, is based on the belief that not all IDUs are ready to discontinue drug use (NIDA, 2000). Harm reduction suggests it is not always necessary to stop the use of illicit drugs but rather reduce the risk of exposure to disease by using harm-reduction methods to reduce the chance of HIV infection among IDUs (Morse et al., 1998). Harm reduction operates under the basic assumption that IDUs are capable of rational, informed choices and when given the knowledge and opportunity to do so, they will choose to reduce harm to themselves as well as to society. (Des Jarlais et al., 1993). It is a non-judgmental approach that accepts drug use as a choice and neither condones or condemns it (Hilton et al., 2001). Harm reduction is based on five principles. It offers a practical alternative that focuses on the consequences of harmful behaviors rather than whether the behavior is morally right or wrong. It accepts alternatives to abstinence. It is based on a 'bottom-up'

approach of patient input and demand, rather than a ‘top-down’ policy. It is user friendly and supports and accepts a ‘low-threshold’ for access to treatment. And finally, it is based on compassionate simplicity and not on moral impracticality (Hilton et al., 2001). Some examples of harm reduction techniques are needle exchange programs, and instruction and encouragement to clean injection equipment (Morse et.al., 1998).

In the National Institute on Drug Abuse Manual: *NIDA Community Based Outreach Model: A Manual To Reduce the Risk of HIV and Other Blood Born Infections in Drug Users*, the following is suggested as a hierarchy of harm reduction to prevention the spread of HIV and Hepatitis C among IDUs:

1. Stop using and injecting drugs
2. Enter and complete drug abuse treatment, including relapse prevention
3. Take the following steps to reduce personal and public health risks, if drug injection continues
 - Never reuse or “share” syringes, water, or drug preparation equipment
 - Use only syringes obtained from reliable sources (e.g., pharmacies, syringe exchange programs)
 - Use a new, sterile syringe to prepare and inject drugs
 - If possible, use sterile water to prepare drugs; otherwise use clean water from a reliable source (such as fresh tap water)
 - Use new or disinfected container (“cooker”) and new filter (“cotton”) to prepare drugs
 - Clean the injection site prior to injection with a new alcohol swab
 - Safely dispose of syringes after one use. (NIDA, 2000)

Montana Injection Drug User Outreach Interventions

Montana's Department of Public Health and Human Service (DPHHS) supports the implementation of HIV and Hepatitis C outreach programs. According to the DPHHS the goal of IDU outreach interventions is to "reduce drug use behaviors that increase the transmission of disease" (Montana HIV Prevention Application, 2002).

The objectives of the outreach programs in Montana include:

1. To have an outreach training curriculum that includes harm reduction education
2. To increase outreach workers' knowledge and understanding of the IDU community through training sessions
3. To increase professionals' knowledge and understanding of the IDU community by training those who deal with IDUs to include HIV preventative services in the treatment plan
4. To have available a resource referral packet for outreach worker's to distribute to their communities
5. To decrease the use of shared IDU equipment through active outreach activities as indicated by the distribution and collection of information through the self-assessment tool (Montana HIV Prevention Application, 2002)

Informational-Motivational-Behavioral Skills (IMB) Model

The Information-Motivation-Behavioral Skills (IMB) model can be used as a basis for understanding HIV risk and prevention. (Fisher and Fisher, 2002). The model, originally developed in response to the HIV epidemic, has been used for understanding and promoting various behaviors including HIV prevention, (Fisher et al., 2002) and health behavior change. (Fisher and Fisher's study as cited in (Fisher and Fisher, in press)). According to the IMB model, HIV prevention information, motivation, and behavioral

skills are the three determinants of HIV preventative behavior. (Fisher et al., 2002). The likelihood that individuals will initiate and maintain patterns of preventative behavior depends on the extent to which individuals are well informed, motivated to act, and possess the behavior skills to act effectively (Fisher and Fisher, 2002). These three determinants are discussed in more detail below.

Information

The first component for HIV preventative behavior skill development and change, according to the IMB model, is the use of information that is directly relevant to HIV transmission and prevention and is easily applied in an individual's social setting (Fisher et al., 2002). HIV preventative information, such as relevant facts about HIV and Hepatitis C as well as information about transmission that is closely related to preventative behavior enactment can serve as a guide for personal preventative actions and behavioral change (Fisher and Fisher, 2002).

Often times, IDUs develop misconceptions about HIV and Hepatitis C risk (Habib, 2003; Feldman and Biernacki, 1998). For example, IDUs tend to exhibit a sense of invulnerability related to contracting HIV and Hepatitis C and repeatedly perceive others, not themselves, to be at risk (Morse et. al., 1998). This suggests a deficiency of knowledge about HIV and Hepatitis C (Habib, 2003). Studies show IDUs who were knowledgeable about the risks associated with injection practices began making changes in their behaviors to reduce their risks (Feldman and Biernacki, 1998). HIV and Hepatitis C prevention interventions for IDUs should include educational programs to educate and

correct misconceptions about HIV and Hepatitis C and to promote safer drug use practices (Habib, 2003).

Motivation

The second component for HIV and Hepatitis C behavioral change according to the IMB model, motivation, takes into account HIV preventative behavior as well as HIV and Hepatitis C preventative motivation. The motivational component determines whether well-informed individuals will be inclined to act on what they know concerning HIV and Hepatitis C prevention. The likelihood of an IDU engaging in preventative behavior is dependent on both personal and social motivation (Fisher and Fisher 2002), as well as, personal perceptions of vulnerability to HIV and Hepatitis C infection (Rosenstock, 1996).

According to the IMB model, personal motivation can be influenced by internal as well as external factors (Fisher and Fisher, 2002). Internal factors are directly related to an individual's motivation to avoid risk behavior (Habib, 2003). Individual perceptions of control, and self-efficacy can influence motivation to abstain from drug use or engage in harm reduction practices (Tortu et al. 2003).

Along with internal motivational factors, external motivational factors are important components of HIV preventative behavioral change (Fisher and Fisher, 2002). Social interventions are frequently cited as important motivational activities to stop the spread of HIV and Hepatitis C infection (Habib 2003; Nelson et al., 2002; Morse et al., 1998; Valentine and Wright-DeAguero, 1998; Greenberg, et al., 1996). IDUs' social correlates, such as their peer and community networks, as well as their social support can

influence HIV and Hepatitis C related behavior (Habib 2003; Nelson et al., 2002; Morse et al., 1998; Greenberg, et al., 1996.) IDUs injection practices can depend on the number and the type of social contacts he or she might have. For example, in a study by Habib (2003), IDUs who shared needles and syringes were much more likely to have shared within their immediate social circle (regular sexual partner, close friend, or family members) than with a stranger (Habib, 2003). Another interesting finding is that IDUs with fewer social contacts (low-density personal networks) are more likely to engage in risky behaviors (Latkin et al., 1995). Additionally, research findings suggest that the role of social support has a different effect on IDU women as compared to IDU men. Abdul-Quader and colleagues, (1990) in a study of IDUs drug and sexual practice, found that women are more positively affected by social support than men (Abdul-Quader et al., 1990). These studies demonstrate that the use of social network analysis may provide valuable insight into the primary social factors affecting the transmission of HIV and Hepatitis C (Morse et, al., 1998)

Drug treatment centers can serve as a positive social network for IDUs (Des and Hubbard, 1999). However, when IDUs enter drug treatment programs and do manage to discontinue drug use, often times, relapse occurs following the completion of the treatment program (Simpson and Marsh, 1986). The chance of relapse can be dependent on whether or not IDUs return to their previous IDU community and previous injection partners and friends, or whether they make entirely new contacts. The probability of relapse after exiting drug treatment is more likely if IDUs make contact and return to their

former social networks, than if an IDU remains in and makes entirely new social networks. (Des Jarlais et al., 1992)

Another important social factor that influences IDU risk behavior is the situation or place that the risk behavior occurs. Injection drug use takes place in a variety of locations. IDUs inject alone or with groups of other IDUs (Des Jarlais et al., 1993). Results from a study by Habib (2003), showed that IDUs are more likely to share needles and other injection equipment when they “hang out” with other IDUs. Habib (2003) also suggests that situational factors such as not wanting to disrupt immediate pleasure can increase the risk of sharing injection equipment and IDU’s perceptions of risks of HIV and Hepatitis C infection at the time (Habib, 2003). This suggests that HIV and Hepatitis C risks appear less significant to IDUs at such times. In order to adequately assess IDUs risk behavior it is critical to understand the importance of IDU’s social support and the social network in which they reside (Habib, 2003).

Behavioral Skills

The third and final component of the IMB model that helps determine whether well-informed and well-motivated individuals will be capable of enacting HIV and Hepatitis C preventative behaviors effectively, is whether or not they have the behavioral skills to do so. Behavioral skills for performing specific HIV and Hepatitis C preventative acts include not only objective skills but also a sense of self-efficacy for practicing HIV and Hepatitis C prevention behavioral skills (Fisher et al., 2002). Individuals who inject drugs must not only be skilled at cleaning injection equipment, but they must also be

skilled at the negotiation of safe injection. HIV and Hepatitis C prevention interventions for IDUs should include educational programs about HIV and Hepatitis C to promote safer drug use practices. However, the development of skills to negotiate safe drug use also should be an important part of these interventions (Habib, 2003).

Outreach Education

Outreach programs can make valuable contributions to preventing blood-borne infections such as HIV and Hepatitis C. Outreach programs are important to HIV and Hepatitis C prevention because they work to enable the IDU population who are unable or unwilling to stop injecting drugs to change the behaviors associated with risk of HIV and Hepatitis C infection (Needle et al., 1998). A typical outreach encounter involves face-to-face communication intended to help IDUs modify their high-risk drug use and sexual behavior. Often times, outreach workers distribute HIV/AIDS and Hepatitis C educational information, bleach kits for disinfecting injection equipment when sterile equipment is not available, and condoms for safer sex (Hilton et al., 2001) They also provide drug users with referrals for drug treatment, syringe access and exchange programs, and HIV, Hepatitis B, and Hepatitis C counseling and testing (NIDA, 2003).

Outreach programs are designed to reach high-risk IDUs and present and reinforce risk behavior prevention messages within the IDU community (NIDA, 2000). Outreach workers are in a unique position to educate and influence their peers to modify their behaviors to reduce the risks for HIV and other blood-borne infections (NIDA, 2003). Outreach programs rely on indigenous outreach workers who generally live in or around

the local community and are familiar with its drug use subculture. Many outreach workers are recovering IDUs themselves, allowing them to draw on their personal experience to relate to other IDUs (NIDA, 2000). In addition, outreach workers usually reflect the ethnicity, gender, and cultural diversity of the drug users targeted for the intervention (NIDA, 2003) as well as having an intimate understanding of IDU's lifestyles (Booth and Koester, 1996).

Even though personal drug experience can positively influence an outreach intervention, it is not an absolute necessity to be successful as an outreach worker. Some important characteristics and abilities of outreach workers include the ability to be able to relate to active drug users on their own terms, the skill to communicate genuine concern and respect for IDUs and their risks, the capacity to be advocates for those at risk by relaying as much information and services as possible, as well as the capability to develop a trusting relationship to IDUs (NIDA, 2000).

Outreach workers should also have appropriate skills and information levels regarding prevention information. This includes a credible knowledge of local resources likely to be of interest to IDUs such as drug treatment programs and services, HIV testing and counseling, syringe exchange programs, and food programs. In addition, outreach workers should possess adequate knowledge of effective ways to reduce the chance of HIV infection and transmission, as well as organizational skills, accurate record keeping abilities, successful networking with groups of individuals at risk, and the ability to recognize and maintain appropriate personal boundaries. Finally, and most importantly

outreach workers must be able to work in the natural environments of drug users and within drug treatment and other service settings, both formally and informally (NIDA, 2000).

More than 15 years of research on HIV/AIDS prevention interventions with IDUs has shown that outreach is effective for different types of IDUs in a variety of different settings (NIDA, 2003). Observational and quasi-experimental studies strongly indicate that outreach programs reach IDUs effectively and help to reduce risk-taking behavior and HIV incidence (Coyle et al., 1998; Des Jarlais et al., 1999) The most effective outreach programs are peer-driven, utilizing indigenous people and users who are trained and paid to assist their peers (Needle et al., 1998). In addition, theoretically based interventions or components have been shown effective at reducing drug-using and sexual risk among IDUs. For example, Sterk and colleagues (2003) performed a study analyzing outreach programs that address sociocultural issues, such as knowledge, motivation and negotiation skills, among African American women IDUs. This study evaluated an intervention based on empirically as well as theoretically based concepts, such as the social-cognitive theory and the theory of reasoned action, to a non-theoretical based standard HIV prevention intervention. The results of this study showed that theoretically based interventions may be more effective than non-theory based standards in reducing the frequency of drug use and the risk behaviors associated with drug use. These results indicate the importance of including theoretical components in interventions designed to reduce the risk of HIV infection among IDUs (Sterk et al., 2003).

In addition, a meta-analysis conducted by Coyle and colleagues (1998) using thirty-six observational and quasi-experimental studies showed consistent findings that outreach-based interventions were effective in reducing HIV risk behaviors among IDUs who participated in such interventions. Following IDUs participation in HIV outreach risk reduction interventions, participants showed significant follow up reductions in measures of drug-related risk behaviors. Some examples of important risk behavior changes include: the termination of injection drug use, a reduction in injection frequency, a reduction in the number of times IDUs reused or shared syringes and other injection equipment, as well as an increased number of IDUs who started to disinfect needles and other injection equipment. In addition, sex-related risk behaviors were reduced as well. The findings provide strong evidence that outreach-based intervention programs are effective for reaching IDUs and provide means for behavior change. A majority of IDUs who participate in outreach programs reduce HIV related behaviors, which may be directly related to a lower incidence of HIV infections (Coyle et al., 1998).

CHAPTER III

Methodology

Description of Target Population

The populations evaluated in this study were injection drug users (IDUs) enrolled in chemical dependency programs in Montana. This population consisted of men and women over the age of 18, who attended the HIV and Hepatitis C prevention outreach program, *Taking it to the Population*.

Study Design

The study consisted of a pre-test, post-test quasi-experimental design. The study was conducted at chemical dependency centers in Montana. Data was collected from the experimental group (*Taking it to the Population* participants) prior to and two weeks after participation in the intervention, and from the control group (non-*Taking it to the Population* participants) at baseline levels and at a two week follow up. This design provided within subject control, i.e. each subject served as his or her own control based on the pre-test score, and between subject control, i.e., the HIV and Hepatitis C prevention outreach program participants were compared to the control participants. This research took place in the spring and summer of 2004. The human subject's application material and consent forms were completed in accordance with The University of Montana Institutional Review Board (IRB) (Appendix A).

Study Sample

Sampling Of Program Participants (Experimental Group)

The experimental group was a convenience sample comprised of volunteers from clients enrolled in the chemical dependency center. The center required all clients to attend the outreach workshop *Taking it to the Population* while they were enrolled in the chemical dependency center; however, the clients were not required to participate in this study. Prior to conducting the HIV and Hepatitis C prevention outreach workshop, the certified HIV and Hepatitis C outreach workers provided participants with a thorough descriptions of the risks and the benefits of participation in the study. After reviewing the risks and benefits and stressing that this study was confidential and the participants' names were not be associated with answers or results of the study, the outreach workers asked for volunteers to participate in the study.

Sampling of Program Participants (Control Group)

The control group consisted of clients who were enrolled in a second chemical dependency treatment center. The control sample was also a convenience sample comprised of volunteers from the second chemical dependency center. At one of the regular group meetings held at the center, the chemical dependency center staff met with the clients and informed them about the risks and benefits of participating in the study, as well as the statement "that as a participant in no way will participant's names be associated with answers or results of this study". The chemical dependency staff then asked for volunteers to participate in this study.

Instrumentation

Survey Instrument

The researchers developed a survey instrument (Appendix B) based on the Informational-Motivational-Behavioral-Skills Model (IMB), a thorough review of literature of IDUs and the determinants of unsafe injection practices, and on examination of existing surveys and surveys. Because of difficulty in measuring the behavioral component of the IMB model in the treatment centers, the researchers measured the participant's intent to change behavior and each participant's self-efficacy of their ability to perform the skills necessary to engage in preventative behaviors. The survey included statements that relate to three major determinants of behavior change:

1. Knowledge of HIV and Hepatitis C
2. Motivation to engage in preventative behaviors
3. Intent and perceptions of efficacy to perform the behavior skills needed to engage in preventative behaviors

There were also six statements that examined IDUs' perceptions about whether it was important to them that outreach workers display the following characteristics: trust, genuine concern, knowledge, respect, and former IDU status. The final section of the survey asked about general demographic information.

Instrument Reliability and Validity

Instrument face and content validity were established through the following procedures. First, the instrument was reviewed by a panel of experts, including two professors with expertise in survey research and HIV prevention, the director of an HIV

and Hepatitis C outreach program, the director of a City AIDS Council, the directors of the two participating chemical dependency centers, as well as several outreach workers within the IDU community. Following suggested revisions, the survey was pilot tested with a segment of the target population who did not participate in the study. Following the pilot test and further revisions, the final draft was completed.

Procedures

Experimental Group

The chemical dependency center required all clients enrolled at the center to attend the one hour HIV and Hepatitis C prevention outreach program, *Taking it to the Population*. Before beginning the study, an outreach worker from *Connection Inc* informed the clients about the purpose of the study and the inherent risks of participating in the study. The clients were then asked to voluntarily participate in the study and complete a pre-test survey before the HIV and Hepatitis C prevention out reach program, and a post test survey that was administered two weeks later. After volunteering to participate in the study, the participants were asked to read and to sign an informed consent (Appendix C), and to fill out the pre-test survey. Participants were asked not to write their names anywhere on the survey, however, they were asked to place a unique identifier on the top of the survey for the purpose of matching pre and post-test surveys. Informed consent forms and surveys were collected separately to prevent names from being connected with the survey data. After the participants completed the pre-test survey, the outreach worker presented *Taking it to the Population* to all of the clients at

the chemical dependency center. *Taking it to the Population* focused on HIV and Hepatitis C risk behavior reduction, which incorporated information about HIV and Hepatitis C transmission and harm reduction, strategies designed to enhance motivation to engage in HIV and Hepatitis C preventative behaviors, and information and strategies designed to influence IDUs' intentions and perceptions to perform HIV and Hepatitis C preventative behaviors.

The participants that finished the chemical dependency treatment program before the two week post-test survey was administered were asked to voluntarily provide the outreach workers with contact information for the purpose of follow-up. The contact information, available only to the outreach worker, was used to mail follow up surveys to the participants who had left treatment and wanted to complete the two week follow up post-test survey. The volunteer participants were asked to return the post-test survey, directly to the researchers at The University of Montana, in a Self Addressed Stamped Envelope.

Two weeks after the pretest survey and the HIV and Hepatitis C prevention outreach program, the outreach worker returned to the chemical dependency center and distributed the post-tests surveys to those individuals that volunteered to complete the pre-test survey and that remained in the treatment center at the time of the follow up. Once again participants were asked not to write their names anywhere on the survey, however, they were asked to place a unique identifier on the top of the survey for the purpose of matching pre and post-test surveys. Upon completion of the survey an

incentive was given to the volunteers for their participation in the study. Since the average stay at the center was five weeks, this process was repeated at three, five-week intervals to gather a larger sample size of intervention group participants. The IDUs who already had participated in the study and who were still enrolled at the chemical dependency center were not allowed to participate in the study a second time.

Control Group

The control group consisted of clients enrolled at a second chemical center in Montana. Staff members from the second chemical dependency directed the administration of the control group's informed consents and the pre- and post-test surveys. At a regularly scheduled meeting that all clients enrolled at center must attend, a staff member from the chemical dependency center informed the clients about the purpose of the study and the inherent risks of participating in the study. The staff member then asked the clients to voluntarily participate as the control group in the study. The clients that voluntarily participated were asked to read and sign the informed consent form, and complete the pre-test survey. Participants were asked not to write their name anywhere on the survey, however, they were asked to write a unique identifier at the top of the survey for the purpose of matching pre and post-tests. To protect confidentiality the consents forms and pre-test surveys were collected separately. The control group participants did not receive any known HIV or Hepatitis C prevention activities between the pre-test and the post-test. Two weeks after the pre-test was administered the staff member at the chemical dependency center asked the clients who voluntarily participated in the pre-test survey to

voluntarily complete a post-test survey. Once again participants were asked not to write their name anywhere on the survey and only to write a unique identifier at the top of the survey for the purpose of matching pre and post-tests. Since the average stay at the center was five weeks, this process was repeated once more, five weeks later, to gather a larger sample size of control group participants. The IDUs who already had participated in the study and who were still enrolled at the chemical dependency center were not allowed to participate in the study a second time.

The Intervention

The experimental intervention consisted of the one-hour HIV and Hepatitis C HIV and Hepatitis C Prevention outreach program *Taking It to the Population*. The program was based on the Informational-Motivational-Behavioral-Skills (IMB) Model which suggests that the likelihood that IDUs will initiate and maintain patterns of HIV and Hepatitis C preventative behavior depends on the extent to which they are well informed, motivated to act, and possess the behavioral skills to act effectively. The intervention was conducted by an indigenous outreach worker who's personal characteristics included the following: the ability to relate to active drug users on their own terms, the skills to communicate genuine concern and respect for IDUs and their risks, the capacity to be an advocate for those at risk by relaying as much information as possible, and the capability to develop a trusting relationship with IDUs. In addition, the outreach worker possessed adequate knowledge of effective ways to reduce the chance of HIV and Hepatitis C infection and transmission, as well as organizational skills, the ability to successfully

network with groups of individuals at risk, and the ability to recognize and maintain appropriate personal boundaries.

The program was comprised of:

1. A participatory opening activity that emphasized the value and self-worth of the individuals in the audience.
2. A personal narrative told by the outreach worker that related her personal struggles with addiction and injection drug use, and her success of overcoming her addiction and staying clean, to the individuals in the audience.
3. Information regarding HIV and Hepatitis C transmission and prevention, accompanied by handouts.
4. Information about harm reduction strategies that could be used in the event of a relapse
5. Information regarding support services and resources for the participants once they were released from the treatment centers
6. A personnel story told by the outreach worker designed to stress the importance of social support and to increase the participants' desire to ask for support for their problems from their social community.
7. A verbal quiz of the audience designed to reinforce their knowledge of HIV and Hepatitis C transmission, prevention strategies, harm reduction, and their feelings of self worth.
8. A final story told by the outreach worker regarding the principles by which she lives to maintain her drug free life. This story was accompanied by a request for the audience to read the principles, from a handout out-loud with her.

Program activities and information was designed to enhance IDUs' knowledge of HIV and Hepatitis C transmission; IDUs' knowledge of how and where to locate HIV and Hepatitis C resources; IDUs' knowledge of harm reduction; IDUs' personal motivation to engage in preventative behavioral interventions; IDUs' perception of their ability to

establish social networks and receive social support outside of their drug community; IDUs' perceptions of their vulnerability to HIV and Hepatitis C associated with personal risk; IDUs' attitudes towards practicing HIV and Hepatitis C prevention interventions; IDUs' perceived efficacy to perform HIV and Hepatitis C preventative interventions; and IDUs' perceptions of ability to resist urgency to inject with other IDUs. Through the above components, the intervention's overall objective was to promote factors that support safer injection behaviors among IDUs' and ultimately reduce the risk for HIV and Hepatitis C.

Statistical Procedures

Data analysis involved comparison of frequency distributions and the modes of variables between the intervention and control groups. T-tests and chi-square tests were used to check the equivalence of the intervention and control groups on demographic variables. Comparison of variables from pretest to posttest was done using analysis of covariance (ANCOVA) with the pretest score for each variable serving as a covariate. A priori the alpha level was set at 0.05. In addition, IMB statements were examined to determine whether an important and practical difference existed between groups from pretest to posttest. This was calculated by scoring each participant's pretest and posttest survey, and taking the absolute value of the pre-post test gain/loss. The scores for both the experimental and control groups were then averaged, and a 12% increase was considered an important between group difference. This indicated that all of the participants answered an average of three more questions correct in the posttest as compared to the pretest.

MANUSCRIPT**Abstract**

A study was conducted to examine the effectiveness of an intervention designed to increase HIV and Hepatitis C preventative behaviors among injection drug users (IDUs) residing in chemical dependency centers. The intervention was developed based on the Informational-Motivation-Behavioral Skills Model (IMB). Seventy IDUs participated in the study. Approximately one-half of the participants received a one-hour HIV and Hepatitis C prevention intervention with an indigenous outreach worker, while the other half did not receive the intervention. A self-report survey was developed and was designed to measure three determinants of HIV preventive behaviors: 1) participants' knowledge of HIV and Hepatitis C prevention, 2) participants' motivation to engage in preventive behavior, and 3) participants' intent and perceptions of efficacy to perform the behavioral skills needed to engage in preventative behaviors. The survey was administered prior to and two weeks after the intervention to evaluate the effectiveness of the intervention. An ANCOVA revealed significant differences ($F=.67, p<.05$) on posttest scores between the two groups. In addition, the intervention group demonstrated important net gains on their average survey scores from pretest to posttest in the information, motivation, and behavioral components, while the control group did not. These findings support the hypothesis that an HIV and Hepatitis C prevention outreach program can be effective in increasing IDUs' knowledge, motivation, and perceived efficacy to perform preventative HIV and Hepatitis C behaviors. This study also

illuminates the need for theoretical based interventions that address HIV and Hepatitis C risk behaviors among IDUs.

Introduction

Human immunodeficiency virus (HIV), the cause of AIDS, is the defining medical and public health issue of our generation and ranks among the greatest infectious disease scourges in history (Fauci, 1999). AIDS, acquired immunodeficiency syndrome, was first reported in the United States in 1981 and has since become a major worldwide epidemic. Since 1981, more than 886,000 cases of AIDS have been reported in the United States and as many as 950,000 Americans may be infected with HIV, one-quarter of whom are unaware of their infection (NIAID, 2003). Equally alarming is the number of Americans infected with the Hepatitis C virus. The Centers for Disease Control reports an estimated 2.7 million Americans are chronically infected with Hepatitis C (CDC, 2002b). An estimated 25,000 people are newly infected with the Hepatitis C virus each year, causing approximately 8,000-10,000 liver disease deaths among those infected (CDC, 2002b).

Injection Drug Use (IDU) is a significant risk factor for AIDS (CDC, 1982) and the single most important risk factor for Hepatitis C infection (CDC, 1998; Garfien et al., 1996). One third, approximately 240,000 of the AIDS cases reported to date, can be attributed to injection drug use (CDC, 2002) while approximately 50 to 95 percent of individuals infected with Hepatitis C report a link to injection drug usage (Garfien et al., 1996). IDUs can introduce HIV and Hepatitis C into their drug community where, through the sharing of needles and injection equipment, the diseases have the ability to

spread rapidly and infect large proportions of individuals who inject and share drugs (Habib, 2003). As a result of the high incidence of HIV and Hepatitis C infection among IDUs, efforts to develop effective preventative interventions to assist IDUs in adopting HIV and Hepatitis C risk reduction behaviors are needed.

There are three common approaches to HIV and Hepatitis C prevention among IDUs (Watters and Guydisk, 1994). The first of these involves punishing IDUs for the illegal use of illicit drugs and using the criminal justice system to remove IDUs from society (Morse et al., 1998). The second major approach involves treating drug use as an illness and using abstinence based treatment approaches through long-term hospitalization, methadone maintenance programs, outpatient, and self help groups (Watters and Guydisk, 1994). The third approach, harm reduction, suggests it is not always necessary to stop the use of illicit drugs but rather reduce the risk of exposure to disease by using harm reduction methods to reduce the chance of HIV infection among IDUs (Morse, et.al., 1998).

Harm Reduction through Outreach

Harm reduction programs are important to HIV and Hepatitis C prevention because they work to enable the IDU population who are unable or unwilling to stop injecting drugs to change their behaviors associated with risk of HIV and Hepatitis C infection (Needle et al., 1998). Outreach is a commonly used harm reduction approach that is designed to decrease the likelihood of transmission of HIV and Hepatitis C among IDUs. A typical outreach encounter involves face-to face communication intended to help

IDUs modify their high-risk drug use and sexual behavior. Outreach programs are designed to reach IDUs and present and reinforce prevention messages within the IDU community (NIDA, 2000). Indigenous outreach workers who generally live in or around the local community and are familiar with its drug use subculture are a key component in outreach programs. Many outreach workers are recovering IDUs themselves and can draw on their personal experience to relate to other IDUs (NIDA, 2000). In addition, outreach workers usually reflect the ethnicity, gender, and cultural diversity of the drug users targeted for the intervention (NIDA, 2003) as well as having an intimate understanding of IDU's lifestyles (Booth and Koester, 1996). Outreach workers are in a unique position to educate and influence their peers to modify their behaviors to reduce the risks for HIV and other blood-borne infections (NIDA, 2003).

More than 15 years of research on HIV/AIDS prevention interventions with IDUs has shown that outreach is effective for different types of IDUs in a variety of different settings (NIDA, 2003; Des Jarlais et al., 1999; Coyle et al., 1998). The most effective outreach programs are peer-driven, utilizing indigenous people and users who are trained and paid to assist their peers (Needle et al., 1998). A meta-analysis conducted by Coyle and colleagues (1998) using thirty-six observational and quasi-experimental studies showed consistent findings that outreach-based interventions were effective in reducing HIV risk behaviors of IDUs who participated in such interventions. Following IDUs participation in HIV outreach risk reduction interventions, participants showed significant follow up reductions in measures of drug-related risk behaviors. Some examples of

important risk behavior changes include: the termination of injection drug use, a reduction in injection frequency, a reduction in the number of times IDUs reused or shared syringes and other injection equipment, as well as an increased number of IDUs who started to disinfect needles and other injection equipment. In addition, sex-related risk behaviors were reduced as well. The findings provide strong evidence that outreach-based intervention programs are effective for reaching IDUs and provide means for behavior change. A majority of IDUs who participate in outreach programs reduce HIV related behaviors, lowering the incidence of HIV infections (Coyle et al., 1998).

Theoretically Based Interventions

Theoretically based interventions have also demonstrated effectiveness in reducing drug-use and sexual risk among IDUs. For example, Sterk and colleagues (2003) carried out a study analyzing outreach programs that address sociocultural issues, such as knowledge, motivation and negotiation skills, among African American women IDUs. This study evaluated an intervention based on empirically and theoretically based concepts, such as the Social-Cognitive Theory and the Theory of Reasoned Action, to a non-theoretical based standard HIV prevention intervention. The results of this study showed that theoretically based interventions may be more effective than non-theory based standards, in reducing the frequency of drug use and the risk behaviors associated with drug use. These results indicate the importance of including theoretical components in interventions designed to reduce the risk of HIV infection among IDUs (Sterk et al., 2003).

The Intervention: Taking it to the Population

The HIV and Hepatitis C Prevention Outreach Program evaluated in this study, *Taking it to the Population*, was developed utilizing the principles of the Informational-Motivational-Behavioral Skills (IMB) Model. The model, originally developed in response to the HIV epidemic, has been used for understanding and promoting various health behaviors (Fisher and Fisher's study as cited in (Fisher and Fisher, in press)). According to the IMB model, HIV prevention information, motivation, and behavioral skills are the three determinants of HIV preventative behavior (Fisher et al., 2002). In other words, the likelihood that individuals will initiate and maintain patterns of preventative behavior depends on the extent to which individuals are well informed, motivated to act, and possess the behavioral skills to act effectively (Fisher and Fisher, 2002). Thus, *Taking it to the Population* incorporates information, motivational strategies, and behavioral skills into the program to enhance the likelihood of positive behavioral change.

Methods

Design

The study was designed to assess whether IDUs who completed the HIV and Hepatitis C Prevention Outreach Program, *Taking it to the Population*, achieved significantly higher post-test scores on the HIV and Hepatitis C Prevention Survey compared to those who did not attend the outreach program. The study used a pre-test, post-test quasi-experimental design. It took place at two chemical dependency centers in

Montana. Data was collected from the intervention group prior to and two weeks after participation in the intervention, and from the control group at baseline levels and at a two week follow up. This design provided within subject control, i.e. each subject served as his or her own comparison based on the pre-test score, and between subject control, i.e., the HIV and Hepatitis C prevention outreach program participants, intervention group, were compared to the control group participants.

Instrumentation

The researchers developed a survey, The HIV and Hepatitis C Prevention Survey, (Appendix B) based on the Informational-Motivational- Behavioral Skills Model (IMB); a thorough review of literature regarding the determinants of unsafe injection practices; and examination of existing surveys. Because of the difficulty in measuring the behavioral component of the IMB model while participants were residing in the treatment centers, the researchers measured the participant's intent to change behavior and their self-efficacy regarding their ability to perform the skills necessary to engage in preventative behaviors. The survey included 24 statements that related to three major determinants of behavior change as suggested by the IMB mode. Participants could respond "Yes", "No", "Not Sure", or "Does not apply to me" to each of the 24 statements. The survey took the participants 10 to 20 minutes to complete. The three components of the IMB Model, which according to the model comprise the determinants of behavior change, along with the survey statements related to each determinant are listed below:

Information Regarding HIV and Hepatitis C Prevention:

1. Knowledge of HIV and Hepatitis C transmission
2. Knowledge of how and where to locate HIV and Hepatitis C resources
3. Knowledge of harm reduction

Motivation to engage in preventative behaviors including:

4. Personal motivation to engage in preventative behaviors
5. Perceptions of vulnerability to HIV and Hepatitis C associated with personal risk
6. Perception of ability to establish social networks and receive social support outside one's drug community
7. Attitudes towards practicing HIV and Hepatitis C prevention interventions

Intent and perceptions of efficacy to perform the behavior skills needed to engage in preventative behaviors including:

8. Perceived efficacy to perform HIV and Hepatitis C preventative behaviors
9. Perceptions of ability to resist urgency to inject with other IDUs

There were also six statements that examined IDUs' perceptions about whether it was important to them that outreach workers display the following characteristics: trust, genuine concern, knowledge, respect, and former IDU status. The final section of the survey contained 23 questions requesting general demographic information.

Instrument face and content validity were established through the following procedure: First, the instrument was reviewed by a panel of experts, including two professors with expertise in survey research and HIV prevention, the director of an HIV and Hepatitis C outreach program, the director of City AIDS Council, the directors of the two participating chemical dependency centers, as well as several outreach workers within the IDU community. Following suggested revisions, the survey was pilot tested with a segment of the target population not participating in the study. Following the pilot test and further revisions, the final draft was completed.

Participants completing both the pretest and the posttest were assigned scores based on the number of correct responses to the 24 (yes/no/not sure/ does not apply to me) statements. For example a perfect score reflecting a high degree of knowledge, motivation, and efficacy to perform HIV and Hepatitis C preventative behaviors would be a 24. If a participant answered half of the questions correctly, he/she would receive a score of 12/24 for an overall score of 50%. "Not sure" was considered a wrong answer, however, if an IDU answered "Does not apply to me" this question was completely factored out of the denominator and the numerator of the total score. For example if an IDU answered 22 questions correctly, and answered the remaining two questions "Does not apply to me" he/she would receive a 22/22 for a total score of 100%.

Subjects

The intervention group consisted of a convenience sample comprised of volunteers from clients enrolled in a pre-release chemical dependency center. The center required all

clients to attend the HIV and Hepatitis C Prevention Outreach Program, *Taking it to the Population*, while they were enrolled at the center; however, the clients were not required to participate in this study. To be eligible, participants had to be 18 years of age or older, and have been an illegal injection drug user at one time. Prior to conducting the HIV and Hepatitis C Prevention Outreach Program, the certified HIV and Hepatitis C outreach workers provided participants with a thorough description of the risks and the benefits of participation in the study. After reviewing the risks and benefits and stressing the anonymous nature of the study, the outreach workers asked for volunteers who were willing to complete the pre and posttests. .

The control group consisted of a convenience sample of volunteers who were enrolled in a second pre-release chemical dependency treatment center. To be eligible, participants had to be 18 years of age or older and have been an illegal injection drug user at one time. At one of the regular group meetings held at the center, the chemical dependency center staff met with the clients and informed them about the risks and benefits of participating in the study, as well as the anonymous nature of the study. The facilitators then asked for volunteers to participate in the control group. .

Intervention

The intervention consisted of a one-hour HIV and Hepatitis C Prevention outreach program, *Taking it to the Population*. The program was developed based on the Informational Motivational Behavioral Skills (IMB) Model which suggests that the likelihood that IDUs will initiate and maintain patterns of HIV and Hepatitis C

preventative behavior depends on the extent to which they are well informed, motivated to act, and possess the behavioral skills to act effectively. The intervention was conducted by an indigenous outreach worker whose personal characteristics included those described in the literature as important to outreach effectiveness such as: the ability to relate to active drug users on their own terms, the skills to communicate genuine concern and respect for IDUs and their risks, the capacity to be an advocate for those at risk by relaying as much information as possible, and the capability to develop a trusting relationship with IDUs. In addition, the outreach worker possessed adequate knowledge of effective ways to reduce the chance of HIV and Hepatitis C infection and transmission, as well as organizational skills, the ability to successfully network with groups of individuals at risk, and the ability to recognize and maintain appropriate personal boundaries (NIDA, 2000).

The program was comprised of:

1. A participatory opening activity that emphasized the value and self-worth of the individuals in the audience.
2. A personal narrative told by the outreach worker that related her personal struggles with addiction and injection drug use, and her success of overcoming her addiction and staying clean, to the individuals in the audience.
3. Information regarding HIV and Hepatitis C transmission and prevention, accompanied by handouts.
4. Information about harm reduction strategies that could be used in the event of a relapse, i.e. how to locate clean injection equipment; how to clean used injection equipment; how to negotiate safer injection practices, etc.
5. Information regarding support services and resources for the participants once they were released from the treatment centers.

6. A personnel story told by the outreach worker designed to stress the importance of social support and to increase the participants' desire to ask for support for their problems from their social community.
7. A verbal quiz of the audience designed to reinforce their knowledge of HIV and Hepatitis C transmission, prevention strategies, harm reduction, and their feelings of self worth.
8. A final story told by the outreach worker regarding the principles by which she lives to maintain her drug free life. This story was accompanied by a request for the audience to read the principles, from a handout out-loud with her.

Program activities and information were designed to enhance IDUs' knowledge of HIV and Hepatitis C transmission; knowledge of how and where to locate HIV and Hepatitis C resources; knowledge of harm reduction; personal motivation to engage in preventative behavioral interventions; perceptions of their ability to establish social networks and receive social support outside of their drug community; perceptions of their vulnerability to HIV and Hepatitis C associated with personal risk; attitudes towards practicing HIV and Hepatitis C prevention interventions; perceived efficacy to perform HIV and Hepatitis C preventative behaviors; and perceptions of ability to resist urgency to inject with other IDUs. Through the above components, the intervention's overall objective was to promote factors that support safer injection behaviors among IDUs' and ultimately reduce the risk for HIV and Hepatitis C.

Procedures

Intervention Group: The chemical dependency center required all clients enrolled at the center to attend the one-hour HIV and Hepatitis C prevention outreach program. Before beginning the study, the outreach worker informed the clients about the purpose of

the study and the inherent risks of participating in the study. The clients were then asked to voluntarily participate. Those who volunteered were asked to read and sign an informed consent (Appendix C), and to fill out the pre-test survey. Participants were asked not to write their names anywhere on the survey, however, they were asked to place a unique identifier on the top of the survey for the purpose of matching pre and post-tests. Informed consent forms and surveys were collected separately to prevent names from being connected with the survey data. After the participants completed the pre-test survey the outreach workers presented the HIV and Hepatitis C prevention program to all of the clients at the chemical dependency center. Two weeks after the pretest survey, the outreach worker returned to the chemical dependency center and distributed the posttest surveys to those individuals that volunteered to complete the pre-test survey and that remained in the treatment center at the time of the follow up. The participants who completed the chemical dependency treatment program before the two week posttest survey was administered were asked to voluntarily provide the outreach workers with contact information for the purpose of follow-up. The contact information, available only to the outreach worker, was used to mail follow up surveys to the participants who had left treatment and wanted to complete the two week follow up post-test survey. Participants were asked to return the post-test survey, directly to The University of Montana, in a self addressed stamped envelope. Since the average stay at the center was five weeks, this process was repeated at three five week intervals to gather a larger sample size of intervention group participants. The IDUs who already had participated in the

study and who were still enrolled at the chemical dependency center were not allowed to participate in the study a second time.

Control Group: The control group consisted of clients enrolled at a second chemical dependency center in Montana. Staff members from the second chemical dependency center were provided explicit verbal and written instructions for the administration of the control group's informed consents and the pre- and post-test surveys. A staff member informed clients about the study during a regularly scheduled meeting. The purpose of the study and the inherent risks of participating in the study were explained at that time. The staff member then asked the clients to voluntarily participate in the control group. The clients that volunteered were asked to read and sign the informed consent form and complete the pre-test survey. As with the intervention group, participants were reminded to not write their names anywhere on the survey, however, they were asked to write a unique identifier at the top of the survey for the purpose of matching pre and post-tests. To protect confidentiality the consent forms and pre-test surveys were collected separately. Two weeks after the pre-test was administered the staff member at the chemical dependency center asked the clients who voluntarily participated in the pre-test survey to voluntarily complete a post-test survey. The control group participants did not receive any known HIV or Hepatitis C prevention activities between the pre-test and the post-test.

Since the average stay at the center was five weeks, this process was repeated five weeks later to gather a larger sample size of control group participants. The IDUs who

already had participated in the study and who were still enrolled at the chemical dependency center were not allowed to participate in the study a second time.

Statistical Methods

Data analysis involved comparison of frequency distributions and the modes of variables between the intervention and control groups. T-tests and chi-square tests were used to check the equivalence of the intervention and control groups on demographic variables. Comparison of variables from pretest to posttest was done using analysis of covariance (ANCOVA) with the pretest score for each variable serving as a covariate. A priori the alpha level was set at 0.05. In addition to an examination of statistical differences, variables were examined to determine whether there existed an important and practical difference between groups from pretest to posttest. This was determined by taking the absolute value of the pre-post test gain of each group. A 12% increase was considered an important difference and indicated that all of the participants answered an average of three more questions correct in the posttest as compared to the pretest

Results

A total of 70 IDUs participated in the intervention or control group procedures. The cohort consisted of 39 intervention subjects and 31 control subjects. Two subjects were eliminated from the study because they reported previous exposure to the intervention. Seventy five percent of those who completed a pre-test also completed a post-test. As illustrated in Table I, the mean age of the participants was 32.10 years ($\sigma = 10.31$), 59% of the participants were male and 73% identified themselves white. Eighty-

one percent of the participants were heterosexual, 47% were married or in a committed relationship, and 61% of the participants had children. Overall there was variability in the level of education, however, sixty-two percent of the population had at least graduated high school or attained a GED. In addition, 49% of the population was unemployed at baseline. One hundred percent of the population had been in jail or prison at one time and 86% of the participants identified themselves as substance users. Sixty-seven percent of the injection drug users stated they had shared injection equipment at one time and a majority of the participants had been tested for HIV/AIDS (87%) and Hepatitis C (89%). Of the participants tested, one participant had tested positive for HIV/AIDS (2%), while 14 participants had tested positive for Hepatitis C (22%). In addition, 29% of the participants had been diagnosed with a mental illness, and 43% were taking prescription medications. Fifty-three percent of the participants had been in a treatment facility only once, while remaining participants had been in a facility two or more times.

Intervention Group vs. Control Group at Baseline

Baseline chi-square tests revealed no statistically significant differences between subjects in the intervention group (n=34) and subjects in the control group (n=31) with respect to all but one demographic variable. There was a significant difference in the number of children reported by the control group as compared to the intervention group. Seventy-seven percent (n=24) of participants in the control group reported having at least one child, while only 49% (n=19) of intervention group participants reported having at least one child at base line level (Table II).

Differences Between Control and Intervention Group

The pretest and posttest scores on the HIV Hepatitis C Prevention Survey were scored twice by the primary investigator to ensure the accuracy of the two scores assigned to each subject. The intervention group that attended *Taking it to the Population* and the control group that received no intervention were compared using analysis of covariance, ANCOVA. Those cases where the participant completed a pretest but not a posttest were omitted from the analysis. Before the inferential statistical data analysis was conducted, the data were evaluated to determine the degree to which the assumptions of ANCOVA were met. All the assumptions were tested at the .05 level. The homogeneity of regression for the covariate pretest scores on the dependent variable posttest scores was similar for the intervention and control groups ($p=.4239$) indicating that the ANCOVA assumption of homogeneity of regression slopes was met. The result of ANCOVA revealed statistically significant improvement from pretest to posttest ($F=.6474$, $p=.0475$) for those who were exposed to the *Taking it to the Population* intervention compared to those who were not. An effect size (ES) of .32 was calculated. The effect size is expressed as the separation between populations due to the independent variable. It increases with greater differences between means and decreases with larger standard deviations (Aron & Aron, 1999). In this study, the ES is interpreted as the proportion of variance explained in the posttest by the pretest scores. Cohen provides a guide for interpreting ES: .20 as small ES, .50 as a medium ES, and .80 as a large ES (Cohen, 1988). Using this criterion, the effect size in this study is small to medium.

Additional examination of the paired pretest and posttest scores found that the intervention group that attended *Taking it to the Population* showed an important gain from the mean pretest (69.5, SD =14.1) to the mean posttest scores (78.2, SD =11.8) as compared to the control group in the pretest (75.7, SD = 13.4) and the posttest (72.7, SD = 16.3). It is interesting to note that the control group demonstrated lower HIV and Hepatitis C Prevention Survey scores at posttest than at pretest.

The significant difference between the intervention and the control group on the HIV Hepatitis C Prevention Survey can be further analyzed in relationship to the three components of the theoretical model used in this study; information, motivation, and behavioral skills. The statements on the survey associated with each component are discussed below in relationship to their contribution to the overall differences between the intervention and control group.

Information

According to the IMB Model, being in possession of adequate information is the first of three primary determinants of HIV preventative behavior change. Information should be directly relevant to HIV transmission and prevention and easily applied in an individual's social setting (Fisher et al., 2002). Nine statements on the survey addressed factors in the informational component. Statements for which there were practical and important gains (gains greater than 12%) in the intervention group are listed in Table IV.

Motivation

Motivation was the second determinant that contributed to the statistically significant difference between the intervention and control groups. The motivational component of the IMB model determines whether well-informed individuals will be inclined to act on what they know concerning HIV and Hepatitis C prevention. Eleven statements on the survey addressed the motivation component that contributed to this gain. Statements for which there were practical and important gains (gains greater than 12%) in the intervention group are listed in Table V.

Behavioral

The third and final determinant that influences whether well-informed and well-motivated individuals are capable of performing HIV and Hepatitis C preventative behaviors effectively is whether or not they have the behavioral skills to do so. Behavioral skills for performing specific HIV and Hepatitis C preventative acts include not only objective skills but also a sense of self-efficacy for practicing HIV and Hepatitis C prevention behavioral skills (Fisher et al., 2002). Individuals who inject drugs must not only feel confident that they have the skills to clean injection equipment, but they must also feel confident that they will be able to negotiate safe injection. Four statements on the survey addressed the behavioral component that contributed to the overall statistical significance in this study. Statements for which there were practical and important gains (gains greater than 12%) in the intervention group are listed in Table VI.

Perceptions of Outreach Workers Characteristics

Participants were also asked their opinion about a variety of outreach worker characteristics that were listed in the literature as important to the success of outreach interventions. Table VII lists the five statements on the survey addressing individual characteristics of outreach workers.

Discussion

This study demonstrates that a one-hour HIV and Hepatitis C prevention program, *Taking it to the Population*, delivered by an indigenous outreach worker can be an effective HIV and Hepatitis C prevention intervention for the IDU population. More specifically, in this study, the intervention positively affected participants knowledge, motivation, and perceived behavioral skills related to HIV and Hepatitis C prevention. Two weeks post intervention, the effects of *Taking it to the Population* had resulted in an overall mean gain of 12% on the HIV and Hepatitis C Prevention Survey in the intervention group as compared to the control group. This suggests that every IDU who participated in *Taking it to the Population* increased his or her score on the HIV and Hepatitis C Prevention Survey by an average of 12% (each participant answered an average of three more questions correctly).

The IMB model was used as a guide to examine specific changes in three behavioral determinants identified by the theoretical model: knowledge, motivation, and behavioral skills. IDUs participating in the intervention demonstrated important gains in mean scores in all three areas.

In the first area identified by the model, information, IDUs became more knowledgeable about how and where to find clean needles. This knowledge is important since IDUs who do not know where to locate clean needles increase the likelihood of sharing equipment. In addition, knowledge of resources to assist with employment and housing, and knowledge of testing locations consistently increased in the intervention group from pretest to posttest.

In the second area identified by the model, motivation, the intervention group participants reported increased motivation to get tested for AIDS and Hepatitis C, increased confidence in the ability to use clean and disinfected injection equipment, as well as increased motivation to practice safer sex. Consistent with previous reports (Habib, 2003; Tortu et al., 2003), the likelihood IDUs will engage in preventative behavior is dependent on personal motivation to avoid risk behaviors and individual attitudes towards abstaining from drug use or engaging in harm reduction practices. Based on our findings, we suggest that HIV and Hepatitis C prevention programs for IDUs in chemical dependency centers should continue to highlight the risk of HIV and Hepatitis C infection and transmission, along with incorporating methods to increase IDUs' motivation to practice preventative behaviors.

The most noticeable changes occurred in the third area described in the IMB Model, intentions and perceptions to perform behavior skills. Post intervention, the participants reported increased intentions to discuss HIV and Hepatitis C with friends. In addition, participants demonstrated enhanced confidence in negotiating clean injection

equipment and an increase in their perception of their ability to refuse a “dirty” needle. Further, participants reported an increased perception of self-control to stop oneself when clean equipment is not available. Consistent with other research (Habib, 2003), this study demonstrates the importance of incorporating a behavioral skills component into interventions that seek to enhance IDUs perceived efficacy to perform HIV and Hepatitis C prevention behaviors and perceived ability to resist urgency to inject with others without sterile equipment.

Perceptions of Outreach Worker Characteristics

Results from this study suggest that it is important that outreach workers demonstrate genuine concern for IDUs, establish a trusting relationship, demonstrate credible knowledge relating to HIV and Hepatitis C, understand that IDUs have the right to make their own decisions about drug use, and show respect for IDUs by understanding their dignity and self worth. Overall, the baseline scores were high, demonstrating IDUs’ opinions and perceptions match previously researched characteristics of outreach workers. In addition, consistent with findings from the National Institute on Drug Abuse (2002), IDUs who participated in this study did not report high scores for the statement of being more comfortable getting information about AIDS or Hepatitis C from outreach workers who are former IDUs. This is an important finding for organizations planning on implementing future programs like this one. An outreach worker who previously injected drugs is not perceived by IDU participants to be an essential component of outreach education as long as the outreach worker is knowledgeable, establishes a trusting

relationship, shows respect, and is genuinely concerned for participants in the outreach program.

In considering the clinical significance and practical value of this study's results, it is important to think about other factors in addition to statistical significance. Service providers considering the adoption of an HIV Hepatitis C prevention intervention, such as *Taking it to the Population*, should note that the program is inexpensive and relatively easy to implement. In addition, it produced a small to medium effect size (.32) around the issue of harm reduction for IDUs, an issue of considerable concern for individuals involved in HIV and Hepatitis C prevention. This effect size, although not large, suggests that changes are happening as a result of the intervention. However, while this program appears to be effective, it must be noted that it is not a quick fix for the complex, multifaceted issue of HIV and Hepatitis C prevention among IDUs. Injection drug users must continue to be exposed to HIV and Hepatitis C prevention strategies that should be reinforced throughout their stay at chemical dependency centers.

Limitations

In order to adequately interpret the results of this study, several limitations must be kept in mind. It was not possible to draw a random probability sample of the IDU population, therefore this study employed a non-probability convenience sample from chemical dependency centers and as a result sampling bias might have occurred. Furthermore, it is clear that this sample is not representative of all IDUs and therefore results may only be generalized to populations similar to this sample. In addition, this

study was made up of a relatively small sample size. The resulting low statistical power interfered with our ability to conduct individual analysis of the three separate components described in the IMB model. This study also relied on self-reported behavior, much like most HIV-behavior change research, and reports of privately occurring activities may be susceptible to inaccuracy and depend on the honesty and willingness of participants to share private information in an anonymous survey.

Another limitation may be the internal validity of the instrument. Unfortunately, only face and content validity were established and the instrument may not accurately measure what it was intended to measure. In addition, the participants were assessed at two points in time and because the follow-up time was only two weeks, it proved difficult to draw conclusions regarding the long-term effects of the intervention. .

Conclusion

As previously mentioned, HIV is the defining medical and public health issue of our generation and ranks among the greatest infectious disease scourges in history (Fauci, 1999). Hepatitis C also is a major public health issue and is the most common chronic blood borne infection in the United States (CDC, 1998). The modes of transmission and methods of prevention for these two diseases are clearly known. Until vaccines preventing the transmission of the two diseases are developed, effective prevention interventions must be developed to help prevent the spread of the viruses. Findings from this study suggest that the intervention, *Taking it to the Population*, may be an effective prevention intervention for individuals who are in treatment for injecting drug use.

In this study, the intervention group participants attended an hour long intervention focusing on information, motivation, and behavioral determinants of HIV and Hepatitis C preventative behavior. The control group did not receive any HIV and Hepatitis C interventions during the length of this study. All participants completed a pretest and a posttest, which provided detailed information on their knowledge, motivation, and perceived efficacy to practice HIV and Hepatitis C preventative behaviors. Outcome results suggest that this intervention positively affected IDUs' overall knowledge of HIV (information), motivation to engage in preventative behaviors, and perceived efficacy to perform preventative behaviors. This outcome was statistically significant and the net gain on the survey between the two groups was important.

Additional research is needed to characterize the durability and the sustainability of this intervention. A larger randomly selected sample would increase the breadth of this study to gain an enhanced understanding of HIV and Hepatitis C preventative behavior change among IDUs. In addition, a longer follow-up period would also assist in drawing improved conclusions regarding the long-term adoptions of safer injection practices to prevent HIV and Hepatitis C among IDUs.

Table I Demographic Measures

Age (years)	70	32.10 [10.314]
Sex		
Male	41	58.6%
Female	29	41.4%
Ethnicity		
White	50	72.5%
American Indian/Alaska Native	11	15.9%
Black or African American	1	1.4%%
Hispanic Latino Chicano	2	2.9%
Asian or Pacific American	1	1.4%
Bi-racial or multiracial/ethnic	4	5.8%
Education		
< High school diploma	11	14.3%
High school diploma / GED	34	62.1%
Trade vocational school	4	5.7%
Some College	19	27.1%
College Graduate	2	2.9%
Graduate/Professional School	1	1.4%
Children (yes)	43	61.4%
Married, or in a committed relationship (yes)	33	47.1%
Sexual orientation		
Heterosexual	57	81.4%
Homosexual	8	11.4%
Bisexual	3	4.3%
Unsure	2	2.2%
Employed (yes)	34	48.6%
Individual yearly Income		
<20,000	44	62.9%
>20,000	20	28.6%
Jail or prison (yes)	70	100.0%
Substance Abuser (yes)	60	85.7%
Shared injection equipment (yes)	47	67.1%
Tested for AIDS (yes)	61	87.1%
Results of AIDS test		
Positive	1	1.6%
Negative	52	85.2%
Don't know	4	6.6%
Tested for Hepatitis C (yes)	62	88.6%
Results of Hepatitis C test		
Positive	14	22.6%
Negative	32	51.6%
Don't know	11	17.7%
Diagnosed with a mental illness (yes)	20	28.6%
Take prescription medicines (yes)	30	42.9%
Number of times in treatment		
1	37	52.9%
2	13	18.6%
3	9	12.9%
4	8	11.4%
5	2	2.9%
6	1	1.4%

Table II Demographic Measures

Variable	Experimental		Control	
	n	% [SD]	n	% [SD]
Age (years)	39	31.28 [10.84]	31	33.52 [9.51]
Sex				
Male	22	56.4%	19	61.3%
Female	17	43.6%	12	38.7%
Ethnicity				
White	28	71.8%	22	71.0%
American Indian/ Alaska Native	5	12.8%	6	19.4%
Black or African American	-	-	1	3.2%
Hispanic Latino Chicano	1	2.6%	1	3.2%
Asian or Pacific American	-	-	1	3.2%
Bi-racial or multiracial	4	10.3%	1	3.2%
Children (yes)	19	48.7%***	24	77.4%***
Education				
< High school diploma	7	17.9%	3	9.7%
High school diploma / GED	16	41.0%	18	58.1%
Trade vocational school	2	5.1%	2	6.5%
Some College	11	28.2%	8	25.8%
College Graduate	2	5.1%	-	-
Graduate/Professional School	1	2.6%	-	-
Married/committed (yes)	15	38.5%	18	58.1%
Sexual orientation				
Heterosexual	32	82.1%	25	80.6%
Homosexual	6	15.4%	2	6.5%
Bisexual	1	2.6%	2	6.5%
Unsure	-	-	2	6.5%
Employed (yes)	20	51.3%	13	41.9%
Individual yearly Income				
<20,000	9	23.2%	11	35.5%
>20,000	26	66.7%	18	58.1%
Jail or prison (yes)	39	100.0%	31	100.0%
Substance Abuser (yes)	33	84.6%	27	87.1%
Shared injection equip. (yes)	28	71.8%	19	61.3%
Tested for AIDS (yes)	35	89.7%	26	83.9%
Results of AIDS test				
Positive	0	0.0%	1	3.8%
Negative	30	85.7%	22	84.6%
Don't know	4	11.4%	-	-
Tested for Hepatitis C (yes)	37	94.9%	25	80.6%
Results of Hepatitis C test				
Positive	7	18.9%	7	22.6%
Negative	18	46.2%	15	56.0%
Don't know	10	25.6%	1	3.2%
Diagnosed w/mental illness (yes)	11	28.2%	9	29.0%
Take prescript. meds (yes)	19	48.7%	11	35.5%
Number of times in treatment				
1	20	51.3%	17	54.8%
2	8	20.5%	5	16.1%
3	5	12.8%	4	12.9%
4	4	10.3%	4	12.9%
5	2	5.1%	-	-
6	-	-	1	3.2%

Table III ANCOVA

Measure	Mean Pretest		Mean Posttest		df	F ratio P value
	Intervention N=39	Control N=31	Intervention N=39	Control N=31		
Total Score on the HIV Hepatitis C Prevention Survey	69.5 (14.1)	75.7 (13.4)	78.2 (11.8)	72.7 (16.3)	1	F=.67 p=.0475

Table IV Knowledge of HIV and Hepatitis C

Knowledge of HIV and Hepatitis C				
	Group	Pretest	Posttest	Net Gain
I know where to get clean injecting equipment needles, cottons, and cookers.	Intervention	66.7%	79.5%	12.8%
	Control	77.4%	77.4%	
When I finish this treatment program I want to contact an organization like <i>Connections, Inc.</i> that will help me find resources such as jobs and housing	Intervention	53.8%	69.2%	21.9%
	Control	58.1%	51.6%	
I know where to get tested for AIDS and Hepatitis C.	Intervention	89.7%	100%	13.5%
	Control	100%	96.8%	

Table V Motivation to Engage In HIV and Hepatitis C Preventative Behaviors

Motivation To Engage In HIV And Hepatitis C Preventative Behaviors				
	Group	Pretest	Posttest	Net Gain
I am confident I will get tested for AIDS and Hepatitis C in the next six months	Intervention	59.0%	74.7%	19.8%
	Control	67.7%	63.3%	
I am confident that if I inject drugs I know how to clean and disinfect needles and cookers and get clean cotton	Intervention	50.0%	71.8%	23.7%
	Control	56.7%	54.8%	
In the future to protect myself against AIDS or Hepatitis C, if I inject drugs, I am confident I can use a clean needle, cooker, and a new cotton to protect myself against AIDS or Hepatitis C.	Intervention	79.5%	82.1%	11.6%
	Control	83.9%	74.9%	
In the future, if I have sex, I will practice safer sex (use condoms).	Intervention	66.7%	78.9%	28.4%
	Control	83.9%	67.7%	

Table VI Intent and perceptions of efficacy to perform the behavior skills needed to engage in preventative behaviors

Intent and perceptions of efficacy to perform the behavior skills needed to engage in preventative behaviors				
	Group	Pretest	Posttest	Net Gain
When I finish this treatment program I plan to discuss AIDS and Hepatitis C with my friends.	Intervention	41.0%	71.8%	34.0%
	Control	54.8%	51.6%	
In the future, if I inject drugs, I would feel comfortable insisting on using clean needles, cottons, and cookers with a friend(s).	Intervention	71.8%	82.1%	13.5%
	Control	80.6%	77.4%	
In the future, if I inject drugs, I would be able to refuse if a friend of mine asked me to inject with a "dirty" needle?	Intervention	66.7%	79.5%	29.0%
	Control	71.0%	54.8%	
In the future, if I inject drugs, I would be able to stop myself from injecting if my friends or I don't have a clean needle?	Intervention	61.5%	66.7%	18.1%
	Control	61.3%	48.4%	

Table VII Perceptions of Outreach Workers Characteristics

	Group	Participants Score
I am more comfortable getting information about AIDS or Hepatitis C if the person who tells me about them is a former Injection Drug User because he or she can relate to me	Intervention	69.2%
	Control	54.8%
It is very important to me that the person who talks to me about AIDS and Hepatitis C is genuinely concerned about me.	Intervention	82.1%
	Control	80.6%
It is very important to me that I can trust the person who talks to me about AIDS or Hepatitis C.	Intervention	89.7%
	Control	90.3%
It is very important to me that the person who talks to me about AIDS and Hepatitis C seems very knowledgeable about ways to reduce AIDS and Hepatitis C infection.	Intervention	100.0%
	Control	90.3%
It is very important to me that the person who talks to me about AIDS or Hepatitis C shows me respect by understanding my dignity and self-worth.	Intervention	100.0%
	Control	83.9%
It is very important to me that the person who talks to me about AIDS or Hepatitis C respects me by accepting the fact that I have the right to make my own decisions about drug use.	Intervention	94.9%
	Control	87.1%

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APPENDIX A
University of Montana Institutional Review Board Application and Approval

1. PURPOSE OF THE RESEACH PROJECT

Introduction

The pandemic of HIV, the precursor to AIDS, is one of the largest infectious disease outbreaks in history, as well as the defining medical and public health issue of our generation. An estimated forty-two million people are currently living with HIV/AIDS. In 2002 alone, approximately five million people were infected with HIV. According to the World Health Organization, about 14,000 new HIV infections are contracted daily. Despite the massive efforts to prevent the spread of HIV, it is estimated that another 45 million people will be infected by the year 2010. Injection Drug use is a risk factor for HIV/AIDS. Of the 886,575 cumulative AIDS cases diagnosed as of 2002, a total of 240,268 occurred among injection drug users (IDUs). Of the 556 cases of HIV/AIDS in Montana, 25% report a direct link with injecting drug use (IDU).

Injection drug use also is the single most important risk factor for Hepatitis C virus infection as well. An estimated 50 to 95 percent of IDUs are infected with Hepatitis C. The Hepatitis C virus (HCV) infection is the most common chronic blood borne infection in the United States. The Centers for Disease Control reports an estimated 2.7 million Americans are chronically infected with Hepatitis C. Most people chronically infected with Hepatitis C do not know they are infected because they may not experience symptoms for 20-30 years after they are infected. An estimated 25,000 people are newly infected with the Hepatitis C virus each year, causing approximately 8,000-10,000 liver disease deaths among those infected.

Effective HIV and Hepatitis C preventative interventions designed to assist IDUs adopt risk reduction behaviors are therefore needed. HIV and Hepatitis C educational outreach programs, such as *Taking it to the Population*, have been used, as HIV prevention strategies for several years in Montana, yet have never been evaluated. In order to fully understand how we can best assist IDUs to decrease their risk for HIV we must evaluate such intervention programs to see if they meet their objectives.

Purpose

The purpose of this study is to determine if *Taking to the Population*, an educational HIV and Hepatitis C prevention outreach program, held at in-patient chemical dependency centers are effective in promoting safer injection practices among injection drug users. The program is based on the Informational Motivational Behavioral skills model which suggests that the likelihood that IDUs will initiate and maintain patterns of HIV and Hepatitis C preventative behavior depends on the extent to which they are well informed, motivated to act, and possess the behavior skills to act effectively.

2. THE SUBJECTS

The human subjects are injection drug users (IDUs) currently enrolled in chemical dependency programs, over the age of 18, at two sites in Montana. The members of this population are not considered physically vulnerable, but there are some concerns over their psychological and social vulnerability due to the stigma attached to their drug usage.

3. RECRUITING SUBJECTS

Sampling of *Taking it to the Population* Participants (experimental group)

The experimental group will consist of clients enrolled in a chemical dependency treatment center in Montana. The center requires all clients to attend the outreach workshop *Taking it to the Population* while they are enrolled in the program. The facilitators of *Taking it to the Population* are certified Hepatitis and HIV educators and will ask for volunteers for the study after providing a thorough description of the risks and benefits of participation in the study.

Sampling of non-educational outreach program participants (control group)

The control group will consist of clients who are enrolled in a second chemical dependency treatment center. At one of the regular group meetings held at the center, the facilitators of *Taking it to the Population* will meet with the clients and inform them about the risks and benefits of participating in the study. The facilitators will then ask for volunteers. A small incentive will be offered to those clients who agree to participate in the study.

4. WHERE THE STUDY WILL TAKE PLACE

The research will be undertaken during the spring and summer semester 2004 in Montana. Workshops will be held and data will be collected at two chemical dependency treatment centers in Montana.

5. ACTIVITIES THE SUBJECTS WILL PERFORM

We will collect information from the experimental group (*Taking it to the Population* participants) prior to and two weeks after participation in the program, and from the control group at a baseline level and at a two week follow up.

Experimental group

The chemical dependency center requires all of its clients to attend the one hour educational outreach program *Taking it to the Population* organized through *Connections Inc.* *Taking it to the Population* focuses on HIV and Hepatitis C risk behavior reduction, which incorporates 1) HIV and Hepatitis C preventative information 2) HIV and Hepatitis C preventative motivation 3) and HIV and Hepatitis C preventative behavior skills. Clients who are in attendance at the program will be asked to voluntarily participate in the study. Before the program begins, study volunteers will be asked to read and to sign an informed consent (please see attached Informed Consent form) and will be given a written and verbal explanation of the purpose of the study (please see attached Explanation of the Study form). They also will be asked to fill out a survey. Informed consent forms and surveys will be collected separately so that no names can be connected with the survey data. Participants will, however, be asked to place a unique identifier on the top of the survey for the purpose of matching pre and posttest surveys. After the program, participants will be asked to voluntarily provide the outreach workers from *Connections Inc.* with contact information.

Two weeks after the program, the facilitators from *Connections Inc* will contact the participants with the follow up survey. Follow-up surveys will be distributed in person to those individuals who remain in the treatment center at the time of the follow up. The “contact information” available only to the *Connections Inc.* outreach worker will be used to mail follow up surveys to those who have left treatment. Participants will be asked to return the survey in a Self Addressed Stamped Envelope. The survey will measure:

- HIV and Hepatitis C transmission knowledge and beliefs,
- knowledge of HIV and Hepatitis C counseling and testing services,
- knowledge of harm reduction techniques,
- motivation to engage in preventative behavior,
- feelings of social support and perceived ability to establish social networks outside of the drug community,
- attitudes towards practicing HIV and Hepatitis C prevention interventions,
- perceptions of personal vulnerability to HIV and Hepatitis C infection,
- perceived self-efficacy to perform preventative measure,
- perceptions of personal ability to negotiate safe drug use, and
- perceived urgency to inject safely (please see attached survey questions).

Control Group

The outreach worker from *Connections Inc.* will attend one of the regularly scheduled meetings at a second chemical dependency treatment center. At that meeting, she will ask clients to voluntarily participate in the study. Those who wish to participate will be given a written and verbal explanation of the study as well as asked to read and sign an informed consent. They will then be asked to complete the survey, and provide *Connections Inc* with contact information where they can be reached two weeks later. Control group participants will be asked to write a unique identifier at the top of the survey for the

purpose of matching pre and posttests. To protect confidentiality the consents forms, surveys, and contact information will be collected separately. These volunteers will not receive any activities between the pre-test and the post-test. Two weeks later *Connections Inc.* will conduct the outreach program *Taking it to the Population* at the treatment center. Prior to the program, the facilitator will ask those individuals who participated in the pre-test to complete a posttest. Posttests will be collected and the clients will receive the prevention program. The “contact information sheet” will be used to contact clients who are no longer at the treatment center. These individuals will be mailed a posttest survey and asked to return it in a Self Addressed Stamped Envelope.

6. BENEFITS OF THE RESEARCH

The Montana Department of Public Health and Human Services (DPHHS) will use the information from this study to plan future HIV intervention programs for IDUs in Montana. This study will provide DPHHS, MCDC, *Connections Inc.*, as well as other health organizations with valuable insight concerning educational outreach programs as an HIV and Hepatitis C intervention tool. Educational outreach programs, such as “*Taking it to the Population*”, that are used as interventions to prevent HIV and Hepatitis C infection have the potential to reach a large number of people in a cost effective way, as well as have the possibility to lower rates of future HIV and Hepatitis C infections. If *Taking to the Population* proves to be effective in promoting safer injection practices and helps IDUs maintain changes, this intervention can easily be replicated in other states and implemented as a useful tool to reduce the spread of HIV infection among IDUs.

7. RISKS AND DISCOMFORTS

- The participant will be asked to disclose information about their injection drug usage and behaviors. Disclosing of this information may be uncomfortable for the participants
- Participants may raise concerns or questions regarding their injection drug usage and related issues.
- Although the survey will be anonymous, the volunteers will be asked to place unique identifiers on each survey for purposes of matching pre- and post-surveys.
- Participants will be asked to disclose of contact information for the purpose of the follow up survey.

8. MEANS TO MINIMIZE EACH SUCH DELETERIOUS EFFECT

- Participants will receive an oral/ and or written explanation of the contents of the survey before they are asked to participate in the study. It will be explained that participation is voluntary. If the content makes any participant uncomfortable, he or

she may chose to withdraw from the study or leave questions unanswered. Participants will be informed of this before answering the survey questions, both by the educational outreach facilitator and in the survey's written instructions.

- If participating in the study raises concerns or questions regarding the individual's injecting drug use, he or she will have access to staff and other resources at the treatment center.
- Volunteers will be explained that participation in the educational outreach program does not require them to participate in the study.
- Volunteers will be asked not to discuss any questions with the other participants in order to protect their confidentiality.
- Volunteers will not be asked to put their name on the survey.
- Contact information will only be used to mail follow up surveys. This information is confidential and only the HIV and Hepatitis C outreach educator who mails the surveys, will have access to it. Upon sending a follow up survey, this information will be destroyed.
- Participants' names will not be linked to the data or results of this study. All data gathered will be looked at as collective data, not individual.

9. PROTECTION OF THE SUBJECT'S PERSONAL PRIVACY

Keeping all information confidential protects participants' privacy. Individuals who participate in this study will asked to read and sign a consent form. No names will appear on the surveys, rather, the volunteers will be asked to place a unique identifier on the pre- and post-test so that the subjects' responses can be matched and compared pre and post. Consent forms will be stored in a separate location from the data, and will be kept in a locked filing cabinet in the Thesis Chair's office, while data will be kept in the graduate assistant's office, in a locked filing cabinet. Participants will be asked to provide a contact address for the purpose of follow up surveys. Only the outreach worker from *Connections Inc.* will have access to the contact information, and it will be destroyed upon mailing of the survey. The names of participants and identifying information will not be associated with the data or with any of the project reports. Maintaining confidentiality reduces the greatest risk to the individual, which is the association of their name with drug usage.

10. WRITTEN CONSENT FORM AND PARTICIPATION INFORMATION SHEETS

See attached subject information and informed consent form

11. WAIVER OF WRITTEN INFORMED CONSENT

Not applicable.



The University of
Montana

#33-04
Office of the Vice President
Research and Development
University Hall 116
(406) 243-6670
(406) 243-6330 Fax

Date: March 4, 2004

To: K. Ann Sondag, HHP

From: Sheila Hoffland, IRB Chair

RE: IRB action on your proposal titled: "AIDS and Hepatitis C Prevention Outreach Intervention"

The modifications to the 11-point summary, participant letter, explanation of the study, and the Informed Consent Form (ICF) satisfactorily address the conditions that the IRB placed on approval of the proposal cited above. Please use the "signed and dated" ICF as the "master" for preparing copies for your study. Approval for this study is granted as of the date of this memo and continues for one year from the date of the Conditional Approval. If the study runs for more than one year, a continuation must be requested. Also, you are required to notify the IRB if there are any significant changes in the study or if unanticipated or adverse events occur during the study.


Sheila Hoffland

Attachment

SUBJECT INFORMATION AND INFORMED CONSENT FORM FOR SURVEY PARTICIPANTS

Title: HIV and Hepatitis C Educational Outreach Programs

Survey Protocol no.: M7625 Funding for this project has been provided by the Montana Department of Public Health and Human Services

Contact Persons: Annie Sondag, Phone 406-243-5215, Health and Human Performance, University of Montana, Missoula, MT 59812; Corey Campbell, Health and Human Performance, University of Montana, Missoula, Mt 59812; Casey Rudd, Phone 406-556-1139, 821 West Minden Hall, Bozeman, MT 59715.

Purpose

The purpose of this study is to determine if *Taking it to the Population*, an educational HIV and Hepatitis C prevention outreach program, held at in-patient chemical dependency centers is effective in promoting safer injection practices among injection drug users. *Taking it to the Population* focuses on HIV and Hepatitis C risk behavior reduction, which incorporates 1) HIV and Hepatitis C preventative information 2) HIV and Hepatitis C preventative motivation 3) and HIV and Hepatitis C preventative behavior skills. The likelihood that individuals will be likely to initiate and maintain patterns of HIV and Hepatitis C preventative behavior depends on the extent to which individuals are well informed, motivated to act, and possess the behavior skills to act effectively

Procedure

Participation in this study is voluntary. If you agree to take part in this research study you will be asked to fill out two surveys, two weeks apart. We ask that you do not put your name on the survey. However, please place the last four digits of your social security number on the survey in order for us to match and compare survey responses pre and post. This survey asks about preventative knowledge, motivation, and behavioral skills relevant to injection drug users. This survey will take about 10 to 15 minutes to complete. All consent forms and data will be stored in separate locked filing cabinets in the project director's office. In no way will the researchers link your identity with the survey.

Risks and Discomforts

- You will be asked to disclose information about your injection drug usage and behaviors. Disclosing of this information may be uncomfortable for you.
- You may be concerned about your privacy and confidentiality. Although your name will not be associated with the information collected for this project, or with any reports, you may have concerns that your identity as a participant in this study will become known.

Methods for reducing risk

- You can withdraw from the project at any time if you feel personal discomfort. If you feel uncomfortable answering a question, you can leave it blank.
- If you would like more information or someone to talk to after the study, the treatment center staff and outreach facilitator will be available to talk with you.
- Your name and identity will not be associated with the data or any of the project reports

Benefits

Your help with this project will provide valuable information to the Montana Department of Public Health and Human Services. By participating in this project, your answers will help staff offer services and develop programs to meet the needs of IDUs in Montana.

Confidentiality

All of the information we collect here today is completely confidential. We will not identify any of the participants. For example, we will not use your name, or any other identifying information in reports or other materials related to this study.

1. Participants' identities will remain anonymous and will not be associated with information in any way.
2. At the conclusion of the study, any information pertaining to participants' identities will be destroyed.
3. Data will be stored in a locked filing cabinet in the researcher's locked office at the University of Montana.
4. All data will be reported as group data; no individual data will be reported.

Compensation for injury

Although we do not foresee any risk in taking part in this study, the following liability states is required in all University of Montana consent forms:

"In the event that you are injured as a result of this research you should individually seek appropriate medical treatment. If the injury is caused by the negligence of the University or any of its employees, you may be entitled to reimbursement or compensation pursuant of the Comprehensive State Insurance Plan established by the department of Administration under the authority of MCA, Title 2, and Chapter 9. In the event of a claim or such injury, further information may be obtained from the University's claims Representative or University Legal Counsel."

Voluntary participation/withdrawal

Your decision to take part in this project is entirely voluntary. You may withdraw from this project for any reasons and at anytime without any penalty.

Questions

If you have any questions about this project now or later, you may contact Annie Sondag; 406-243-5215, or Casey Rudd 406-556-1139.

I have read the above description of this study. I have been informed of the risks and benefits involved, and all of my questions have been answered to my satisfaction. Furthermore, I have been assured that a member of the study team will answer any further questions I may have. I voluntarily agree to take part in this study. I am at least 18 years of age. I understand that I will receive a copy of this consent form.

Signature: _____ Date _____

Thank you very much for your participation!

3/4/04

2/16/05
Kata Hoffland

For Internal Use Only
RECEIVED

PROPOSAL # 33-04
Form RA-108
(Rev. 3/03)

FEB 06 2004

The University of Montana
**INSTITUTIONAL REVIEW BOARD (IRB)
CHECKLIST**

UNIVERSITY OF MONTANA
Vice President for Research
Submit the proposed research of this Checklist, including any required attachments, for each project involving human subjects.
The IRB meets monthly to evaluate proposals, and approval is usually granted for one year. See IRB Guidelines and Procedures for details.

Project Director: K. Ann Sandag Dept.: HHP Phone: 5215
Signature: K. Ann Sandag Date: 2-6-04 E-mail: anna.sandag
Co-Director(s): _____ Dept.: _____ Phone: _____

Project Title: AIDS and Hepatitis C Prevention Outreach Intervention

Project Description: The purpose of this project is to determine the effect of (in non-technical language) an outreach intervention on the knowledge, attitudes and behaviors of injecting drug users in regard to AIDS and hepatitis C prevention.

All investigators on this project must complete the self-study course on protection of human research subjects, available at the UM IRB website: <http://www.umt.edu/research/irb.htm>.

Certification: I/We have completed the course - (Use additional page if necessary)

Signature	Date	Signature	Date
<u>K. Ann Sandag</u>	<u>2-6-04</u>	_____	_____
<u>Cory Campbell</u>	<u>2-6-04</u>	_____	_____

Students Only:
Faculty Supervisor: _____ Dept.: _____ Phone: _____
Signature: _____
(My signature confirms that I have read the IRB Checklist and attachments and agree that it accurately represents the planned research and that I will supervise this research project.)

For IRB Use Only

IRB Determination:

___ Approved Exemption from Review — Exemption # _____

___ Approved by Expedited/Administrative Review

- Full IRB Determination:
 - ___ Approved
 - Conditional Approval (see attached memo)
 - ___ Resubmit Proposal (see attached memo)
 - ___ Disapproved (see attached memo)

Signature IRB Chair: Asteria Hoffland Date: 2/7/04
(over)

#33-04



The University of
Montana

Office of Research
University Hall 116
243-6670
FAX 243-6330

Date: February 19, 2004

To: K. Ann Sondag, HHP

From: Sheila Hoffland, IRB Chair

RE: IRB action on your proposal titled: "AIDS and Hepatitis C Prevention Outreach Intervention"

Attached is the IRB Checklist, which shows that the IRB at its February 17, 2004 meeting gave "Conditional Approval" to your proposal. Once the conditions have been satisfied and this has been reported back to the IRB, final approval to initiate the project will be granted. A revised Informed Consent Form, along with the other paperwork, will need to be returned. I will place a "date stamp approval" and return it to you. This will then be used as a "master" for making your copies. The conditions are as follows:

Participant Letter:

- The first use of IDUs should have it spelled out, in case the individual is not familiar with the term.
- A coding method other than the last four numbers of a Social Security # should be used.

Informed Consent Form:

- Protection of the Subject's Personal Privacy, 6th sentence: It indicates a "graduate assistant's office" but nowhere else in the proposal does it include a graduate assistant. Please clarify.
- Voluntary Participation/Withdrawal: Expand this section to include a statement regarding the participant can withdraw without any penalty.

Explanation of the Study:

- Is this explanation being given pre- or post-survey?
- 4th sentence: The survey cannot be confidential and anonymous at the same time. Please change the wording.


Sheila Hoffland
IRB Chair

APPENDIX B
HIV Prevention Intervention Survey 2004

AIDS and Hepatitis C Prevention Outreach

Dear Participant,

Thank you for taking the time to participate in this survey. This survey asks about knowledge, motivation, and behaviors relevant to injection drug use. The results will be used to help develop future AIDS and Hepatitis C educational outreach programs for people who use injection drugs and to assess whether or not the programs make a difference. The Montana Department of Health and Human Services (DPHHS) is also interested in using the results in their AIDS and Hepatitis C prevention work. Most importantly, by participating in the study you can assist other people who use injection drugs in benefiting from HIV and Hepatitis C prevention outreach programs in the future.

Instructions:

Your participation is entirely voluntary. If you feel uncomfortable answering a question, just leave it blank. However, the more fully and honestly you do answer, the more help your survey will be to organizations who do AIDS and Hepatitis C prevention work. This is a completely anonymous survey. Do not put your name anywhere on these forms. However, please circle the month you were born, and write the first three letters of your mother's first name at the top of the survey. If you have any questions, please ask one of the facilitators who will be happy to help you.

Only the researchers from The University of Montana conducting this study will have access to the data. No personal information will be disclosed or appear in any report. For the purpose of matching follow up surveys, your answers will be tracked only by code number. Should you have any questions or concerns, please ask the person handing out the survey or contact one of the researchers.

We want to thank you again for taking the time to participate in this study, which is funded by the Montana Department of Public Health Human Services; STD/AIDS Section. Your participation is greatly appreciated and valued.

Sincerely,

Corey Campbell, Researcher
The University of Montana

Annie Sondag, Researcher
The University of Montana

Code Number**Please circle the month you were born:**

Jan. Feb. March April May June July Aug. Sept. Oct. Nov. Dec.

AND Write the first three letters of your mother's first name: _____

Please fill out these questions by circling the answer that best describes your response to each statement. Please give your first response, and don't spend too much time on any one item.

1. A person can get infected with AIDS or Hepatitis C by injecting drugs with a clean, sterile needle.	Yes	No	Not Sure
2. A person can get AIDS or Hepatitis C by injecting with a dirty needle.	Yes	No	Not Sure
3. A person can get AIDS or Hepatitis C by sharing ink used for tattooing.	Yes	No	Not Sure
4. A person can get AIDS or Hepatitis C by having sex with someone who has shared needles, cookers, or cotton.	Yes	No	Not Sure
5. You can usually tell whether or not someone has AIDS or Hepatitis C by looking at them.	Yes	No	Not Sure
6. I know where to get clean needles, cottons, and cookers.	Yes	No	Not Sure
7. When I am not in treatment I know how and where to get help from people like addiction counselors, outreach workers and public health workers.	Yes	No	Not Sure
8. When I finish this treatment program I want to contact an organization like <i>Connections, Inc.</i> that will help me find resources such as jobs and housing.	Yes	No	Not Sure
9. I know where to get tested for AIDS and Hepatitis C.	Yes	No	Not Sure
10. I am confident I will get tested for AIDS and Hepatitis C in the next six months.	Yes	No	Not Sure
11. I am concerned about whether I get AIDS or Hepatitis C because my health is very important to me.	Yes	No	Not Sure
12. When I finish this treatment program I will probably hang out with friends who inject drugs.	Yes	No	Not Sure
13. When I finish this treatment program, I feel like I can ask my non-using friends and family for help with my problems.	Yes	No	Not Sure

Please fill out these questions by circling the answer that best describes your response to each statement

14. I am not at risk for AIDS or Hepatitis C because if I inject drugs, I always inject safely.	Yes	No	Not Sure	Does not apply to me
15. I am not at risk for AIDS or Hepatitis C because if I inject drugs, I know the people I share my needles, cottons, and cookers with don't have AIDS or Hepatitis C.	Yes	No	Not Sure	Does not apply to me
16. I am confident that if I inject drugs I can always get clean needles for injecting.	Yes	No	Not Sure	Does not apply to me
17. I am confident that if I inject drugs I can always use a clean needle, cooker, and cotton.	Yes	No	Not Sure	Does not apply to me
18. I am confident that if I inject drugs I know how to clean and disinfect needles and cookers and get clean cotton.	Yes	No	Not Sure	Does not apply to me
19. In the future to protect myself against AIDS or Hepatitis C, if I inject drugs, I plan on using a clean needle, cooker, and a new cotton to protect myself against AIDS or Hepatitis C.	Yes	No	Not Sure	Does not apply to me
20. In the future, if I have sex, I will practice safer sex (use condoms).	Yes	No	Not Sure	Does not apply to me
21. When I finish this treatment program I plan to discuss AIDS and Hepatitis C with my friends.	Yes	No	Not Sure	Does not apply to me
22. In the future, if I inject drugs, I would feel comfortable insisting on using clean needles, cottons, and cookers with a friend(s).	Yes	No	Not Sure	Does not apply to me
23. In the future, if I inject drugs, I would be able to refuse if a friend of mine asked me to inject with a "dirty" needle?	Yes	No	Not Sure	Does not apply to me
25. In the future, if I inject drugs, I would be able to stop myself from injecting if my friends or I don't have a clean needle?	Yes	No	Not Sure	Does not apply to me
26. I am more comfortable getting information about AIDS or Hepatitis C if the person who tells me about them is a former Injection Drug User because he or she can relate to me.	Yes	No	Not Sure	Does not apply to me
27. It is very important to me that the person who talks to me about AIDS and Hepatitis C is genuinely concerned about me.	Yes	No	Not Sure	Does not apply to me
28. It is very important to me that I can trust the person who talks to me about AIDS or Hepatitis C.	Yes	No	Not Sure	Does not apply to me

- | | | | | |
|---|-----|----|-------------|-------------------------|
| 29. It is very important to me that the person who talks to me about AIDS and Hepatitis C seems very knowledgeable about ways to reduce AIDS and Hepatitis C infection. | Yes | No | Not
Sure | Does not
apply to me |
| 30. It is very important to me that the person who talks to me about AIDS or Hepatitis C shows me respect by understanding my dignity and self-worth. | Yes | No | Not
Sure | Does not
apply to me |
| 31. It is very important to me that the person who talks to me about AIDS or Hepatitis C respects me by accepting the fact that I have the right to make my own decisions about drug use. | Yes | No | Not
Sure | Does not
apply to me |

FOR THE NEXT QUESTION, PLEASE CHECK THE BOX THAT FITS YOU BEST

32. After completing this treatment program, I am confident that the frequency of my drug use will be:
- Never Infrequent Frequent

Demographics

Please answer the following questions about yourself.

33. Age: _____ years

34. Biological Sex (sex at birth):

- Male Female

35. What is your sexual orientation?

- Heterosexual/straight Homosexual/Gay or Lesbian
 Bisexual Unsure

36. Are you married or in a committed relationship? Yes No

37. Do you have children? Yes No.

If yes, 1 2 3 4 5 6 7+

38. What is the highest level of education you have completed?

- Less than high-school Some college
 High School Graduate/GED College Graduate
 Trade Vocational School Graduate/Professional School

39. Are you employed or do you have other regular income?

- Yes No

40. Which of the following categories represents your individual yearly income (the amount you would claim on your income tax forms)?

- | | |
|--|--|
| <input type="checkbox"/> 100,000+ | <input type="checkbox"/> 20,001 – 35,000 |
| <input type="checkbox"/> 75,001 -100,000 | <input type="checkbox"/> 10,001 - 20,000 |
| <input type="checkbox"/> 50,001 - 75,000 | <input type="checkbox"/> 6,000 - 10,000 |
| <input type="checkbox"/> 35,001 - 50,000 | <input type="checkbox"/> < 6,000 |

41. Have you ever been in jail or prison?

- Yes No

42. Are you a substance user?

- Yes No

If so what substance? _____

43. Have you ever injected drugs?

- Yes No

44. Have you ever shared injection equipment?

- Yes No

45. Have you been tested for AIDS?

- Yes No

If so what were the results? Positive Negative Don't know

46. Have you even been tested for Hepatitis C?

- Yes No

If so what were the results? Positive Negative Don't know

47. Have you ever been diagnosed with a mental illness?

- Yes No

If yes, which one? _____

48. Do you take prescription meds?

- Yes No

If yes, which ones? _____

49. How many times have you been to treatment?

- 1 2 3 4 5 6 7+

APPENDIX C
Informed Consent Form

SUBJECT INFORMATION AND INFORMED CONSENT FORM
for Survey Participants

Title: HIV and Hepatitis C Educational Outreach Programs

Survey Protocol no.: M7625 Funding for this project has been provided by the Montana Department of Public Health and Human Services

Contact Persons: Annie Sondag, Phone 406-243-5215, Health and Human Performance, University of Montana, Missoula, MT 59812; Corey Campbell, Health and Human Performance, University of Montana, Missoula, Mt 59812; Casey Rudd, Phone 406-556-1139, 821 West Minden Hall, Bozeman, MT 59715.

Purpose

The purpose of this study is to determine if *Taking it to the Population*, an educational HIV and Hepatitis C prevention outreach program, held at in-patient chemical dependency centers is effective in promoting safer injection practices among injection drug users. *Taking it to the Population* focuses on HIV and Hepatitis C risk behavior reduction, which incorporates 1) HIV and Hepatitis C preventative information 2) HIV and Hepatitis C preventative motivation 3) and HIV and Hepatitis C preventative behavior skills. The likelihood that individuals will be likely to initiate and maintain patterns of HIV and Hepatitis C preventative behavior depends on the extent to which individuals are well informed, motivated to act, and possess the behavior skills to act effectively

Procedure

Participation in this study is voluntary. If you agree to take part in this research study you will be asked to fill out two surveys, two weeks apart. We ask that you do not put your name on the survey. However, please place the last four digits of your social security number on the survey in order for us to match and compare survey responses pre and post. This survey asks about preventative knowledge, motivation, and behavioral skills relevant to injection drug users. This survey will take about 10 to 15 minutes to complete. All consent forms and data will be stored in separate locked filing cabinets in the project director's office. In no way will the researchers link your identity with the survey.

Risks and Discomforts

- You will be asked to disclose information about your injection drug usage and behaviors. Disclosing of this information may be uncomfortable for you.
- You may be concerned about your privacy and confidentiality. Although your name will not be associated with the information collected for this project, or with any reports, you may have concerns that your identity as a participant in this study will become known.

Methods for reducing risk

- You can withdraw from the project at any time if you feel personal discomfort. If you feel uncomfortable answering a question, you can leave it blank.
- If you would like more information or someone to talk to after the study, the treatment center staff and outreach facilitator will be available to talk with you.
- Your name and identity will not be associated with the data or any of the project reports

Benefits

Your help with this project will provide valuable information to the Montana Department of Public Health and Human Services. By participating in this project, your answers will help staff offer services and develop programs to meet the needs of IDUs in Montana.

Confidentiality

All of the information we collect here today is completely confidential. We will not identify any of the participants. For example, we will not use your name, or any other identifying information in reports or other materials related to this study.

1. Participants' identities will remain anonymous and will not be associated with information in any way.
2. At the conclusion of the study, any information pertaining to participants' identities will be destroyed.
3. Data will be stored in a locked filing cabinet in the researcher's locked office at the University of Montana.
4. All data will be reported as group data; no individual data will be reported.

Compensation for injury

Although we do not foresee any risk in taking part in this study, the following liability states is required in all University of Montana consent forms:

"In the event that you are injured as a result of this research you should individually seek appropriate medical treatment. If the injury is caused by the negligence of the University or any of its employees, you may be entitled to reimbursement or compensation pursuant of the Comprehensive State Insurance Plan established by the department of Administration under the authority of MCA, Title 2, and Chapter 9. In the event of a claim or such injury, further information may be obtained from the University's claims Representative or University Legal Counsel."

Voluntary participation/withdrawal

Your decision to take part in this project is entirely voluntary. You may withdraw from this project for any reasons and at any time without any penalty.

Questions

If you have any questions about this project now or later, you may contact Annie Sondag; 406-243-5215, or Casey Rudd 406-556-1139.

I have read the above description of this study. I have been informed of the risks and benefits involved, and all of my questions have been answered to my satisfaction. Furthermore, I have been assured that a member of the study team will answer any further questions I may have. I voluntarily agree to take part in this study. I am at least 18 years of age. I understand that I will receive a copy of this consent form.

Signature: _____ Date _____

Thank you very much for your participation!

APPENDIX D
Explanation of the Study

EXPLANATION OF THE STUDY

This study is an outcome evaluation of the HIV and Hepatitis C prevention educational outreach program called “Taking it to the Population”. We have developed a survey that asks about knowledge, motivation, and behaviors relevant to injection drug use. This is a completely anonymous survey. The following are possible risks and discomforts associated with participation in this study.

- You will be asked to disclose information about your injection drug usage and behaviors. Disclosing of this information may be uncomfortable for you.
- You may raise concerns or questions regarding your injection drug usage and related issues. This may be uncomfortable for you.
- Volunteers will be asked to place their name and contact address on a separate sheet of paper. This contact information will only be used to mail follow up surveys. This information is confidential and **only** Casey Rudd, the HIV and Hepatitis C outreach educator, will have access to it. (Correction Connections, the University of Montana, Montana DPHHS will not have access to this information). Upon sending a follow up survey, this information will be destroyed.
- Volunteers will be asked to place unique identifiers on each survey for purposes of matching pre- and post-surveys.

The results will be used to help us refine future HIV and Hepatitis C educational outreach programs for IDUs and assess the outcome of participating in these HIV and Hepatitis C educational outreach programs. The Montana Department of Health and Human Services (DPHHS) is also interested in using the results in their HIV and Hepatitis C prevention work. Most importantly, by participating in the study you can assist other IDUs in benefiting from educational outreach programs such as this one.

Only the researchers from the Health and Human Performance Department at the University of Montana conducting this study will have access to this data. No personal information will be disclosed or appear in any report. For the purpose of mailing follow up surveys, if you chose you will have to disclose your contact information. When the data have been fully analyzed, a summary of the results will be available for volunteers to read through the HHP department at the University of Montana.