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Strategies to Improve Access to and Utilization of Health Care Services and Adherence to Antiretroviral Therapy Among HIV-Infected Drug Users

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Abstract

We review five innovative strategies to improve access, utilization, and adherence for HIVinfected drug users and suggest areas that need further attention. In addition, we highlight two innovative programs. The first increases access and utilization through integrated HIV and opioid addiction treatment with buprenorphine in a community health center, and the second incorporates adherence counseling for antiretroviral therapy in methadone programs. Preliminary evaluations demonstrated that these strategies may improve both HIV and opioid addiction outcomes and may be appropriate for wider dissemination. Further refinement and expansion of strategies to improve outcomes of HIV-infected drug users is warranted.

Keywords

drug treatment; HIV; access to care; health care utilization; adherence to antiretroviral therapy; integrated treatment; outreach; case management; directly observed therapy; peer support; patient navigation; adherence counselors

BACKGROUND

Over the last decade, advances in HIV treatment have led to individuals with HIV living longer (Centers for Disease Control and Prevention, 2008). These advances have also contributed to HIV-infected drug users living longer lives, necessitating chronic and coordinated management of drug abuse,¹ HIV disease, and related medical sequelae. To realize the full potential of advances in HIV treatment, drug users must first access and utilize health care services and then achieve near-perfect adherence to antiretroviral therapy. Achieving these goals has been challenging because medical care and drug treatment are traditionally delivered in separate settings by different providers. More recently, newer

Declaration of Interest

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¹The journal's style utilizes the category *substance abuse* as a diagnostic category. Substances are used or misused; living organisms are and can be *abused*. Editor's note.

treatment models and innovative strategies have emerged to improve treatment outcomes. The availability of integrated models that provide both HIV and drug treatment in the same setting and the emergence of other innovative strategies to facilitate access, utilization, and adherence have great potential to improve health care and health outcomes for HIV-infected drug users.

Studies have demonstrated that, compared with other risk groups, HIV-infected drug users are less likely to access needed medical care (Cunningham, Sohler, Berg, Shapiro, & Heller, 2006; Fleishman et al., 2005; Giordano et al., 2005; Shapiro et al., 1999), the first crucial step in achieving optimal HIV and drug treatment outcomes. Further, when they do access medical care, HIV-infected drug users are more likely to have suboptimal utilization of HIV health care services (Fleishman et al., 2005; Shapiro et al., 1999), less likely to receive antiretroviral therapy (Celentano et al., 1998, 2001; Cohen et al., 2004; Kalichman, Graham, Luke, & Austin, 2002; Pulvirenti et al., 2003; Strathdee et al., 1998; Turner et al., 2001), more likely to experience delays in initiating antiretroviral therapy (Ding et al., 2005), and more likely to be prescribed suboptimal antiretroviral regimens (Celentano et al., 2001). Most studies that examine access to and utilization of health care services do not differentiate which drugs are used by study participants and instead report on "current drug use" or "past drug use" as measures that combine many types of drugs into one category. The few studies that do differentiate among "drugs of abuse" in study participants demonstrate that poor access to and utilization of health care services is particularly problematic for cocaine users, who are less likely to use antiretroviral therapy compared with other drug users (Cejtin et al., 1999; Cunningham et al., 2006; Kalichman et al., 2002; Metsch et al., 1999; Metsch, Pereyra, & Brewer, 2001; Palacio, Shiboski, Yelin, Hessol, & Greenblatt, 1999).

HIV-infected drug users who access care and are prescribed antiretroviral therapy are then faced with the challenging task of achieving near-perfect adherence. This is a crucial goal for all HIV-infected individuals, as near-perfect adherence helps to improve overall health and prevent the development of drug-resistant HIV strains. Adherence to antiretroviral therapy is generally lower in active drug users than in either former drug users or nondrug users (Malta, Strathdee, Magnanini, & Bastos, 2008). Again, active stimulant (cocaine or methamphetamine) use, in particular, is associated with poor adherence (Arnsten et al., 2002; Crisp, Williams, Timpson, & Ross, 2004; Hinkin et al., 2007; Ingersoll, 2004; Lucas, Cheever, Chaisson, & Moore, 2001; Moss et al., 2004; Sharpe, Lee, Nakashima, Elam-Evans, & Fleming, 2004; Tucker, Burnam, Sherbourne, Kung, & Gifford, 2003). However, these patterns appear to be reversible, as substance abuse treatment has been associated with improved adherence (Kapadia et al., 2008; Palepu et al., 2006; Spire, Lucas, & Carrieri, 2007).

Despite a growing body of research on access, utilization, and adherence in HIV-infected drug users, much remains unknown. Detailed data about the influence of specific substances of abuse (e.g., cocaine versus heroin) and specific patterns of use (e.g., daily versus binge use) on either utilization or adherence have only recently been reported (Berg et al., 2004; Cook et al., 2001; Cunningham et al., 2006; Halkitis, Kutnick, & Slater, 2005; Kalichman et al., 2002; Metsch et al., 1999, 2001). Data comparing utilization or adherence outcomes associated with different types of drug treatment programs are also lacking. Further, rigorous evaluations of the effectiveness of newly emerging models of integrated care and other innovative strategies are just becoming available. Despite the recent emergence of novel treatment models, a thorough exploration of the potential effects of these programs on access, utilization, and adherence among HIV-infected drug users has not been conducted.

Many studies that have examined strategies to improve access, utilization, and adherence among HIV-infected drug users have been conducted in New York City (NYC). There are many unique aspects of NYC that have probably contributed to the relative abundance of studies that focus on drug use and HIV infection in NYC. When compared with any other city in the United States, NYC has by far the largest number of individuals living with HIV/ AIDS (Centers for Disease Control and Prevention, 2008). Of these HIV-infected individuals, a substantial proportion are also drug users (New York City Department of Health and Mental Hygiene, 2009). Thus, providers and administrators working in HIV programs in NYC have had to develop strategies that successfully engage drug-using patients in their programs. In addition, for decades, NYC has been the epicenter of the heroin epidemic and has played a central role in the crack epidemic (Frank, 2000; Frank & Galea, 1996). As such, NYC has a large number of drug treatment programs. For example, more outpatient methadone maintenance treatment programs (MMTPs) are located in NYC than in any other city (Substance Abuse and Mental Health Services Administration, 2009). Similar to HIV programs, these drug treatment programs have been among the first to include innovative strategies to improve health care outcomes among drug users who are infected with HIV (Selwyn, Budner, Wasserman, & Arno, 1993). Therefore, given the epidemiology of HIV infection and drug use in NYC, it is not surprising that a substantial amount of important research focusing on improving access, utilization, and adherence outcomes among HIV-infected drug users has originated in NYC.

This article is divided into two parts. In the first section, we highlight several strategies that are key components of successful interventions to improve access to and utilization of HIV care and adherence to HIV treatment among HIV-infected drug users. In the second section, we present two unique programs that incorporate innovative strategies to address challenges associated with providing high-quality medical care for HIV-infected drug users and are examples of the novel approaches that have grown out of the large health care demands of HIV-infected drug users in NYC. One program aims to improve access to and utilization of health care services by providing integrated HIV and opioid addiction treatment in a Bronx community health center (CHC). The other program aims to improve adherence to antiretroviral therapy by providing adherence counseling in a Bronx MMTP with on-site primary and HIV medical care. The overarching goal of this article is to provide health care providers, program developers, policy makers, and researchers with (1) a landscape of successful strategies that have been developed and evaluated to improve health outcomes for HIV-infected drug users and (2) suggestions about areas of future research to further refine these strategies to improve access, utilization, and adherence among HIV-infected drug users.

REVIEW OF KEY STRATEGIES TO IMPROVE ACCESS, UTILIZATION, AND ADHERENCE AMONG HIV-INFECTED DRUG USERS

Several innovative strategies have been adopted or developed to improve care for HIVinfected drug users. Here we review five strategies that have demonstrated successes in clinical and/or research settings, including integration of HIV and drug treatment, provision of interdisciplinary care focusing on case management, directly observed antiretroviral therapy, support groups, and peer-based interventions. It is not our intention to provide a comprehensive or exhaustive discussion of all available strategies. Instead, our objective is to review the most commonly studied programs that can help guide those caring for HIVinfected drug users.

Integration of HIV and Drug Treatment

In the United States, HIV treatment and drug treatment have traditionally been provided in separate clinical sites by different health care providers. This presents numerous challenges for patients attempting to access, utilize, and adhere to treatment for these comorbid conditions. Programs in NYC were among the first to demonstrate the feasibility of integrating HIV and drug user treatment in the same setting and that integrated treatment leads to improved patient outcomes (Selwyn et al., 1993). Treatment can be integrated by offering drug treatment in HIV treatment settings, as demonstrated by the first program described below, or by offering HIV treatment in drug treatment settings, as demonstrated by the second program described below. Both types of integration have been shown to be effective.

Integration of HIV and drug treatment is beneficial for several reasons (Samet, Friedmann, & Saitz, 2001). First, integrated treatment increases the number of available sites for both types of care, making it easier for HIV-infected drug users to access and utilize health care services. Second, drug treatment has been shown not only to reduce illicit drug use but also to improve health behaviors and HIV clinical outcomes (Palepu, Horton, Tibbetts, Meli, & Samet, 2004). Third, allowing a single medical provider to monitor both prescription and illicit drug use may reduce the occurrence of adverse drug–drug interactions, such as the known adverse effects of coadministration of methadone and many antiretroviral medications (Altice, Friedland, & Cooney, 1999; Bart et al., 2001; Beauverie, Taburet, Dessalles, Furlan, & Touzeau, 1998; Clarke, Mulcahy et al., 2002; Clarke et al., 2001a, 2001b; Gerber et al., 2001; McCance-Katz, Farber, Selwyn, & O'Connor, 2000; McCance-Katz, Rainey, Friedland, & Jatlow, 2003; Shelton et al., 2004; Stevens, Rapaport, Maroldo-Connelly, Patterson, & Bertz, 2003). Finally, integration of care is likely to decrease duplication of services and may therefore be more efficient and less costly.

Integration of drug treatment into the HIV primary care setting became possible only recently. Since the Drug Addiction Treatment Act of 2000, physicians can treat opioid addiction outside of drug treatment settings, using buprenorphine. While this opportunity was met with enthusiasm from many providers and policy makers, adoption of this model in clinic settings has been slow (Cunningham, Kunins, Roose, Elam, & Sohler, 2007). Thus, few data are available to evaluate this model. Two small recent studies describing the provision of buprenorphine treatment to HIV-infected individuals in primary care settings demonstrate that this model is not only feasible but also associated with positive health outcomes (see below; Sullivan, Barry et al., 2006). This model of care will be further examined by an ongoing multisite study evaluating the integration of HIV and buprenorphine treatment in clinical settings across the United States. Despite promising initial data, research exploring reasons for the reluctance of more widespread adoption of this model has revealed a number of challenges at patient, provider, and service system levels (Cunningham, Kunins, et al., 2007; Sullivan, Tetrault, Bangalore, & Fiellin, 2006; Turner, Laine, Lin, & Lynch, 2005). This underscores the need for large-scale, focused research of integrated drug treatment models for HIV primary care settings.

Compared with offering drug treatment in HIV primary care settings, programs that integrate HIV treatment into drug treatment settings have a longer history of success, are gaining acceptance, and have increasingly been implemented across the United States. The provision of HIV treatment in MMTPs, which was first described in NYC, has particular advantages. These advantages include the following: the frequency of visits required by MMTPs, which allows for multiple opportunities for provider–patient interactions; the capability of providing directly observed therapy (described below); and the ability to closely monitor drug–drug interactions occurring between methadone and antiretrovirals. Studies evaluating these programs demonstrate that patients receiving HIV care in MMTPs

have high levels of health care and antiretroviral utilization and improved HIV-related health outcomes (see below; Selwyn et al., 1993).

The integration of HIV and drug treatment is gaining acceptance as a successful component of health care for HIV-infected drug users (Samet et al., 2001). Available data support the adoption of such models; however, models integrating drug treatment into HIV primary care settings are relatively new and experimental and will require adaptation and refinement to be successful and appropriate for widespread dissemination.

Interdisciplinary Care: Case Management

Interdisciplinary care for HIV-infected drug users can facilitate access to and utilization of a wide array of health and social services needed by HIV-infected drug users (Willenbring, 2005). Interdisciplinary care includes the provision and coordination of care by several types of providers, including physicians, mental health providers, pharmacists, adherence counselors, substance user counselors, outreach workers, and case managers, each of whom may address different aspects of patients' health. In this section, we focus on case management and describe its association with access, utilization, and adherence.

The term "case management" has been applied to a range of different services, and case managers vary greatly in their duties and qualifications. According to the Case Management Society of America (2007), case management is defined as assessment, planning, facilitation, and advocacy for options and services to meet individuals' health needs. In HIV case management, the focus is generally on improving access to medical care and coordinating service delivery, but this focus has been modified for specific populations, including drug users (Emlet & Gusz, 1998; Malone & Osborne, 2000). Despite the lack of clarity and specificity of the goals and services associated with HIV case management, case managers are commonly employed in programs targeting HIV-infected drug users. In fact, of the many types of services available in HIV treatment programs, case management is among the most common. In 2005, the Ryan White CARE Act allocated over \$130 million (12% of its total budget) to case management services (Health Resources Services Administration, 2007a, 2007b). Although case management has widespread acceptance among health care providers and policy makers as a successful component of HIV care, research findings to date are less certain.

Observational research that includes HIV-infected drug users overwhelmingly demonstrates positive associations between the use of case management and HIV health care utilization and antiretroviral adherence (Cunningham, Sohler, et al., 2007; Harris et al., 2003; Katz et al., 2001; Kushel et al., 2006; Lo, MacGovern, & Bradford, 2002; Magnus et al., 2001; Messeri, Abramson, Aidala, Lee, & Lee, 2002; Sherer, 1998). However, the few published experimental studies of case management have produced conflicting results, leaving uncertainty about the efficacy of case management. For example, in one randomized trial of drug users and nondrug users newly diagnosed with HIV, those who received case management had improved HIV care utilization at both 6 and 12 months (Gardner et al., 2005). In another trial targeting HIV-infected drug users, those who received case management did not have better HIV care utilization patterns than those who received a brief control intervention (Sorensen et al., 2003).

Outreach

Many clinical and social service programs that care for HIV-infected drug users include outreach services (Health Resources Services Administration, 2007a, 2007b). Outreach services often aim to assist patients obtain optimal HIV care. Like case management, outreach services encompass a variety of different activities and are conducted by people

with a range of expertise and training. For example, outreach services can range from sending letters or making phone calls to patients to visiting patients in their homes or communities. People who are responsible for conducting outreach can range from peers to physicians (Cunningham, Sanchez, Heller, & Sohler, 2007). Because of this broad use of the term "outreach," it is difficult to draw conclusions about whether outreach to HIV-infected drug users is associated with improvements in access to and utilization of health care services or with medication adherence.

Similar to case management, many providers and policy makers strongly support the use of outreach to facilitate drug users' engagement in HIV care. We developed a program in which physicians joined a community-based organization's outreach team visiting HIV-infected drug users in single-room occupancy hotel residents in the Bronx, New York. Single-room occupancy hotels were targeted because homeless HIV-infected men and women are housed by NYC in these settings. We found that, after exposure to our medical outreach program, the number of individuals who reported having HIV primary care providers and taking antiretroviral medication significantly increased (Cunningham et al., 2005). In a related program that provides HIV care to a target population that consists predominantly of drug users, we found that outreach services were positively associated with utilization of HIV health care services obtained at a local CHC (Cunningham, Sanchez, Li, Heller, & Sohler, 2008). A larger multisite study that included our NYC site demonstrated that individuals who had at least nine outreach contacts over 3 months had better HIV primary care services utilization patterns than individuals who had fewer than nine outreach contacts (Cabral et al., 2007).

Innovative outreach programs have targeted drug users to improve health care utilization and antiretroviral adherence outside of NYC as well. One program demonstrated that drug users who used services within a mobile needle-exchange-based health care program had a reduction in emergency room visits (Pollack, Khoshnood, Blankenship, & Altice, 2002). Another study found that in an intensive case management program that used outreach to link ex-offenders into HIV care, 82% of ex-offenders continued to receive HIV care at 1 year (Rich et al., 2001). Finally, as described below, several programs providing directly observed antiretroviral therapy through community outreach demonstrate improved adherence and virologic outcomes among drug users (Altice et al., 2004; Jayaweera et al., 2004; Ma et al., 2008; Macalino et al., 2004; Mitchell, Freels, Creticos, Oltean, & Douglas, 2007; Wohl et al., 2004).

In summary, outreach services are already included in many programs caring for HIVinfected drug users. Outreach services include a broad range of creative strategies to reach HIV-infected drug users and meet their health care needs. A range of well-documented outreach strategies are available for program administrators and providers to draw from. While data support the benefits of many outreach programs, much conceptual work is needed to clearly define different outreach models and evaluate their relative efficacy and effectiveness across settings.

Directly Observed Therapy

Directly observed therapy (DOT) is an adherence-improving strategy in which health care providers or other program staff directly observe patients taking their medication. The first DOT programs were developed for tuberculosis; they demonstrated improvements in medication adherence and clinical response and reductions in the risk of developing drug resistance (Chaulk & Kazandjian, 1998; Weis et al., 1994). Because these same goals apply to antiretroviral therapy, DOT programs have been extended to HIV treatment and often target HIV-infected drug users. Pilot studies have demonstrated the feasibility and acceptability of DOT programs for HIV treatment in settings such as community locations

(Altice et al., 2004; Jayaweera et al., 2004; Ma et al., 2008; Macalino et al., 2004; Mitchell et al., 2007; Wohl et al., 2004), public HIV clinics or shelters (Garland et al., 2007; Tinoco et al., 2004), prisons (Babudieri, Aceti, D'Offizi, Carbonara, & Starnini, 2000), and methadone maintenance clinics (Clarke, Keenan, Ryan, Barry, & Mulcahy, 2002; Lucas, Weidle, Hader, & Moore, 2004; McCance-Katz et al., 2002).

Two models of community-based antiretroviral DOT programs for active drug users have been studied in randomized trials. One evaluated DOT provided by an outreach worker who met participants at a location of their choice to deliver and observe each antiretroviral dose (Macalino et al., 2007). Compared with standard adherence support, DOT was significantly associated with greater odds of viral suppression and improvement in CD4 counts over a 3month follow-up period.

A second model provided antiretroviral DOT in an existing community health care van that made regular, predetermined stops in four inner-city neighborhoods to administer and observe participants' antiretrovirals (Altice et al., 2004). Participants were randomized to self-administer medication (control) or to receive DOT for one daily dose of antiretrovirals from the van for a 6-month period (intervention). Evening doses were provided to DOT participants daily, and evening dosing was prompted with a reminder from a beeper. Compared with participants in the control group, those in the DOT group were significantly more likely to achieve a decrease in HIV viral load and an increase in CD4 count.

Settings with infrastructures that allow frequent contact with drug users, such as prisons (Babudieri et al., 2000) or MMTPs (Conway et al., 2004; Lucas et al., 2004), are promising venues for DOT programs. Observational studies conducted with MMTP-based DOT programs suggest they are feasible and acceptable and improve rates of viral suppression (Clarke, Keenan, et al., 2002; Conway et al., 2004; Lucas et al., 2006). However, to date, no experimental studies of DOT programs in MMTPs have been published. We are conducting a randomized trial evaluating the efficacy of 6 months of DOT administered in MMTPs throughout the Bronx. Preliminary analyses indicate that, compared with control participants who self-administered antiretrovirals, participants randomized to DOT have improved adherence and decreased HIV viral load (Arnsten et al., 2007).

Data on the benefits of antiretroviral DOT are emerging and suggest that providers and policy makers who care for HIV-infected drug users should consider this approach. However, practical challenges to DOT programs have been documented. For example, it is possible that ongoing drug use may negatively impact retention in or efficacy of MMTP-based DOT programs, but the available data on this are inconclusive. While one study showed that cocaine use was associated with poor adherence to supervised doses of antiretrovirals and with discontinuation of DOT (Lucas et al., 2007), another study showed that neither cocaine nor heroin use affected viral suppression during DOT (Conway et al., 2004). Additional research is needed to develop and evaluate strategies that can address challenges associated with adopting DOT programs specifically for HIV-infected drug users.

Support Groups

Peer-based support groups affiliated with programs for HIV-infected drug users aim to provide education, emotional and practical support, and skills training to participating members. Few studies have explicitly studied the effect of support groups on HIV outcomes among drug users; however, support groups are widely accepted by both providers and patients and address the needs of HIV-infected drug users that are not met by other services. Small studies that have examined support groups and included HIV-infected drug users support these impressions.

Two studies demonstrated that participation in HIV support groups had a positive impact on mental health outcomes, physical health outcomes, and HIV-related risk behaviors (Kelly et al., 1993; Summers et al., 2000). Another study found that attending HIV support groups was associated with high utilization of antiretroviral medications among Hispanic drug users (Kang, Goldstein, & Deren, 2006). We implemented a program integrating HIV care into a community-based drop-in center that serves drug users in the Bronx (Mund et al., 2008). In our evaluation of specific components of the program, we found that use of support groups was positively associated with utilization of HIV care services (Cunningham, Sanchez, et al., 2008).

Despite the paucity of rigorous evaluation of support groups, their widespread use across clinical and social service settings indicate that they probably provide benefits that have not yet been adequately described or evaluated. These are areas that merit further investigation.

Peer-Based Interventions

Peers are involved in numerous programs for HIV-infected drug users. Peers are thought to bridge communication between patients and providers because they are more likely than providers to have concordant social, economic, and health backgrounds with patients. Peers also improve sustainability of programs because they are less expensive to employ. Despite these obvious benefits, research evaluating the efficacy and effectiveness of peer-based interventions is scarce.

Patient navigation is one emerging model in which peers address disparities in care among marginalized individuals, such as HIV-infected drug users. Much like other strategies, patient navigation lacks a standard definition. Patient navigators are often peers who are "culturally matched," have similar health challenges, and often assist with logistical barriers to accessing care. (Dohan & Schrag, 2005; Fowler, Steakley, Garcia, Kwok, & Bennett, 2006). We are aware of only one study examining peer-based patient navigation that included HIV-infected drug users (Bradford, Coleman, & Cunningham, 2007). This study pooled data from four patient "navigation-like" programs that blended outreach, care coordination, and accompaniment to appointments. Over a 12-month follow-up period, compared with individuals who did not have navigators, those who had patient navigators had greater improvements in HIV health care utilization and viral load suppression.

Other peer-based interventions have been developed and evaluated. In one study of a peerdriven intervention, HIV-infected drug users acted as health advocates for other HIVinfected drug users, providing peer support and counseling weekly over a 6-month period (Broadhead et al., 2002). Those who acted as health advocates were simultaneously assigned their own peer health advocates. Drug users who both provided and received peer support improved their adherence to HIV appointments and medications. In contrast, in a large multisite randomized trial of drug users, a peer-based mentoring intervention demonstrated no effect on health care utilization, antiretroviral adherence, or HIV risk behaviors (Purcell et al., 2007). In another randomized trial of a 3-month peer-based social support intervention targeting patients in an NYCHIV clinic, results were similarly negative. That study revealed no difference in antiretroviral adherence or HIV viral load between the intervention and control groups (Simoni, Pantalone, Plummer, & Huang, 2007).

Although peer-based interventions appear to play an increasing role in programs that provide care to HIV-infected drug users, the data evaluating peer-based programs are conflicting. This is probably due to the range of different models that have emerged and the limited number of formal evaluations that are available. As data that evaluate and compare different peer-based models become available, researchers will be in a better position to describe characteristics of successful peers, the type of peer training needed, the services

PROVIDING INTEGRATED CARE TO HIV-INFECTED DRUG USERS: DESCRIPTIONS OF TWO PROGRAMS

Below we report preliminary evaluations of two ongoing programs that incorporate the strategies discussed above, highlighting the provision of integrated HIV and drug treatment. We developed these programs to improve access to and utilization of health care services and antiretroviral adherence among HIV-infected drug users in NYC. One program integrates drug treatment into an HIV primary care setting, while the other program integrates HIV adherence treatment into a drug treatment setting.

Program 1: Integrated HIV and Opioid Addiction Treatment With Buprenorphine

In January 2006, as part of a multisite study funded by the Health Resources and Services Administration (HRSA), we developed an integrated HIV and opioid addiction treatment program in a CHC in the Bronx. The study is evaluating integrated versus nonintegrated treatment, comparing HIV and substance use outcomes between the two groups. Participants in the integrated treatment group receive HIV treatment and opioid addiction treatment with buprenorphine/naloxone by the same physician at the CHC. Participants in the nonintegrated treatment group receive HIV treatment at the CHC and opioid addiction treatment at a nearby affiliated drug treatment program.

HIV treatment is the same for both groups and is provided at the CHC. Guided by national treatment guidelines, HIV treatment is offered by one of three general internists who are experienced HIV providers. In addition, as needed, referrals by the primary HIV provider are made to a dedicated interdisciplinary HIV team at the CHC, consisting of an adherence counselor, a clinical pharmacist, a nutritionist, a social worker, and a psychiatrist.

Opioid addiction treatment differs between the two groups. Participants in the integrated treatment group receive opioid addiction treatment with buprenorphine/naloxone at the CHC (Cunningham, Giovanniello, et al., 2008). In this setting, buprenorphine treatment is guided by one of the same three experienced HIV physicians described above. The HIV pharmacist also plays a central role in buprenorphine treatment at the CHC, facilitating buprenorphine induction, stabilization, and maintenance treatment with oversight by one of the three physicians. At the CHC there are no substance user counselors or drug treatment groups to facilitate behavior change among participants; therefore, the three physicians were additionally trained to incorporate motivational interviewing (MI) techniques into routine medical visits. For example, if participants continue to use heroin intermittently while receiving buprenorphine treatment, the physicians typically reflect to participants about their heroin use, clarify with participants how important and/or problematic their ongoing heroin use is perceived, encourage participants to establish goals regarding heroin use, and then encourage them to develop a plan to reach their goals. In addition to using these MI techniques, participants who need additional psychosocial support are referred to individual or group counseling in other community settings.

Opioid addiction treatment for the nonintegrated group is provided at a nearby drug treatment program and consists of buprenorphine, methadone, or nonpharmacologic treatment. The specific treatment modality is determined collaboratively by the participant and the staff at the substance abuse treatment program. Unlike typical methadone treatment, buprenorphine treatment at the drug treatment program does not require daily visits, on-site medication dispensing, or a pre-specified schedule of urine toxicology tests. Instead, it is

similar to buprenorphine treatment in the CHC, in which participants' visit schedules and urine toxicology testing are based on clinical judgment, and prescriptions for buprenorphine/ naloxone are filled by community pharmacies.

Inclusion criteria for study participation include (1) opioid dependence per the *Diagnostic* and Statistical Manual of Mental Disorders—Fourth Edition (DSM–IV) criteria (American Psychiatric Association, 1994), (2) HIV infection, and (3) interest in opioid addiction treatment. Exclusion criteria include (1) current buprenorphine treatment for more than 30 days, (2) pregnancy, (3) alcohol or benzodiazepine dependence per the *DSM–IV* criteria (American Psychiatric Association, 1994), (4) abnormal liver function, (5) current suicidal ideation, and (6) >30 mg/day of prescribed methadone. In November 2006, the last criterion was changed to >60 mg/day of prescribed methadone.

For this evaluation, study participants were enrolled between 2006 and 2008 and are followed for 6 months, and data are collected from interviews and medical records. Interviews are conducted at baseline and after 1, 3, and 6 months, using audio-computer-assisted self-interview (ACASI) technology. Interview data include sociodemographic information, drug use behaviors (McLellan et al., 1992), depressive symptoms (Radloff, 1977), and health status (Ware, Kosinski, & Keller, 1996). Medical record data include number of health care visits, CD4 count data (lab value of CD4 count and the number of CD4 count tests taken), and lab value of HIV viral load. The main study outcomes were substance use behaviors (self-reported opioid, cocaine, alcohol, and injection drug use), HIV clinical outcomes (lab value of CD4 count, lab value of HIV viral load, and health status), and health care utilization (number of health care visits and number of CD4 count tests taken).

Although the study was initially designed as a randomized trial, we discontinued randomization because many participants who were randomized to nonintegrated treatment crossed over to integrated treatment. We suspect two main reasons for this pattern. First, to obtain buprenorphine treatment at the drug treatment program, participants are required to have one of only two insurance plans, while at the CHC, numerous insurance plans are accepted for buprenorphine treatment. Second, most participants who presented to the CHC for opioid addiction treatment preferred to receive this treatment at the drug treatment at the design included randomization, many participants were unwilling to receive opioid addiction treatment at the drug treatment program. Therefore, we are analyzing the data using a "per protocol" analysis strategy, including participants in the group corresponding to the treatment they received, even if they were initially randomized to a different treatment group. Our main analyses examines whether participants in the two groups had different outcomes at 6 months.

In our preliminary analyses, 163 potential participants who were opioid-dependent sought opioid addiction treatment and were interested in the study. Of this group, 131 were ineligible for the following reasons: 105 were HIV-negative; 14 did not return for full screening assessments; 6 did not speak English; 3 were taking methadone doses that exceeded the eligibility criterion; 1 had been taking buprenorphine for more than 30 days; 1 was alcohol-dependent; and 1 was actively suicidal. Of the 32 who were eligible, 2 withdrew shortly after enrollment, and 1 was lost to follow-up. The final sample for this preliminary analysis includes the 29 participants who were enrolled in the study for 6 months.

The majority of participants were male, black or Hispanic, unemployed, injecting drugs, and actively using heroin and cocaine (see Table 1). Over 6 months, participants in both groups had substantial decreases in their substance use (including heroin, cocaine, alcohol, and

injection drug use). HIV clinical outcomes (change in the lab values of CD4 count and HIV viral load) appeared to improve more among those receiving integrated versus nonintegrated treatment. Health care utilization (number of visits and number of CD4 count tests taken) was statistically significantly higher among those receiving integrated versus nonintegrated treatment.

These preliminary data demonstrate that opioid-dependent individuals who receive integrated HIV and buprenorphine treatment in a CHC can improve health care utilization and health outcomes. In this analysis, both groups had substantial decreases in their substance use, but participants who received integrated (vs. nonintegrated) treatment appeared to have greater improvements in their HIV clinical outcomes and health care utilization. Although conclusions drawn from these data must be tempered because of the small sample size and potential for selection bias, these findings can help guide the delivery of health care to opioid-dependent HIV-infected individuals. These results add to the one other published study of integrated HIV and buprenorphine treatment that demonstrated that this model of integration is associated with decreased substance use, HIV, and health care utilization outcomes (Sullivan, Barry et al., 2006). Our findings are also consistent with other research previously described that demonstrated that integration of HIV and drug user treatment, in general, is an important strategy that can improve targeted treatment outcomes among HIV-infected drug users.

Program 2: Support for Treatment Adherence Readiness Program

The Support for Treatment Adherence Readiness (STAR) Program was established in 2004 to improve antiretroviral adherence among HIV-infected drug users attending an MMTP with on-site HIV and primary medical care. Located in the Bronx, the MMTP includes 12 distinct clinics located in 6 different neighborhoods. Each clinic uses the same treatment paradigm, which relies on integrating HIV and primary medical care, drug treatment, and mental health services in one location. The STAR Program further exemplifies the incorporation of an innovative HIV-related treatment service into a drug treatment setting.

The STAR Program was designed to be comprehensive flexible and was integrated into the usual treatment of drug users. The specific objectives of the STAR Program are as follows: (1) to provide individualized adherence readiness training prior to beginning or restarting antiretrovirals; (2) to assess and monitor self-reported medication adherence, barriers to adherence, and adherence self-efficacy; (3) to provide individualized adherence support to patients taking antiretrovirals; and 4) to increase the proportion of patients achieving and maintaining an undetectable viral load. To implement the STAR Program, four paraprofessional adherence counselors were trained in MI and congitive behavioral skills techniques (CBST) to provide six semistructured 30- to 45-minute adherence counseling sessions for each patient.

The STAR Program is based on the information– motivation–behavior skills model of behavior change (Fisher, Fisher, Bryan, & Misovich, 2002; Fisher, Fisher, Misovich, Kimble, & Malloy, 1996; Fisher, Fisher, Williams, & Malloy, 1994). This model asserts that information is necessary but insufficient to alter behavior and that motivation and behavioral skills are critical determinants in promoting behavior change. The intervention incorporates brief MI and CBST to promote the skills necessary to create behavioral change.

The first two sessions of the STAR Program intervention are MI-driven and semistructured and focus on assessing adherence obstacles, determining stage of change, eliciting change talk, determining triggers for nonadherence, and developing treatment goals. The following four sessions are more CBST-driven and focus on HIV adherence education and skill development, tailored to a patients' needs and goals. These sessions include structured

modules to facilitate skill building (e.g., communicating with providers and coping with side effects). Adherence counselors also work to identify unaddressed mental health, substance use, financial, vocational, or housing issues that potentially impede HIV medication adherence, and they collaborate with the interdisciplinary treatment team (physician, physician's assistant, and substance user counselor) to provide appropriate intervention and referrals. The final session focuses on relapse prevention and identifying future goals. After completion of the six sessions, patients are provided with "booster sessions" as needed and are eligible to begin the counseling cycle again if circumstances change (e.g., they start a new medication regimen).

All patients enrolled in the MMTPs who are eligible for highly active antiretroviral therapy (or HAART, whether prescribed or not) are eligible for the STAR Program. Patients are referred by their physicians and substance user counselors or recruited by the adherence counselors. During the first STAR Program visit, patients are asked about demographic information, mode of HIV transmission, CD4 count, viral load, psychiatric diagnoses, symptoms of depression, substance use, and antiretroviral medication use. Those who are prescribed antiretroviral medications are asked names of medications, how often they miss doses, and methods used to remember taking medications. During subsequent sessions, patients indicate if they are taking their prescribed antiretroviral medications and how well they adhered to the medications during the past month, week, and 3 days. After program enrollment, every 3 months we attempt to collect information on CD4 count, viral load, symptoms of depression, substance use, antiretroviral medication use, and antiretroviral adherence during the past week and 3 days. However, completing these follow-up assessments is not a requirement for participating in the program.

From 2004 to 2008, 315 patients have enrolled in the STAR Program and have completed an average of 4.81 (SD = 4.54) adherence counseling sessions. Although most STAR Program participants have been in the program for at least 3 months, we have baseline and 3- month follow-up data available for approximately 106. In Table 2, we present baseline and 3-month follow-up data on these patients. Half are male, and the majority are Hispanic. Almost all patients were diagnosed with HIV infection more than 3 years prior, with injection drug use as the most common risk behavior. Compared with baseline, 3 months after enrolling in the STAR Program, a smaller percentage of patients missed any antiretroviral doses during the past 3 days (30.8% vs. 18.5%, p= .13) or in the past week (42.1% vs. 28.0%, p = .12). Additionally, compared with baseline, over 3 months, HIV viral load significantly decreased (median log viral load = 3.7 vs. 3.2, with interquartile range [IQR] = 1.9-4.7 and 1.9-4.4, respectively; p < .01); a significantly smaller percentage of patients reported sadness (74.3%) vs. 58.0%, p < .05); a significantly smaller percentage of patients reported lack of enjoyment in life (45.2% vs. 29.0%, p < .05); and patients experienced significantly fewer symptoms of depression (median number of symptoms = 5.0 vs. 4.0, with IQR = 3.0-7.0and 2.0–6.8, respectively; p < .05).

While the evaluation of the STAR Program is ongoing, several preliminary conclusions may be drawn from these data. First, providing antiretroviral adherence counseling in an MMTP is feasible. Second, as demonstrated by over 300 patients enrolling in the STAR Program, patients are receptive to and interested in antiretroviral adherence counseling. Third, incorporation of adherence counseling into drug treatment programs can be associated with improved HIV-related physical health and well-being among drug users. While our study was limited by the lack of a comparison group and the potential for selection bias, combined with other studies, our findings suggest that the STAR Program is a successful model that might be successfully integrated into other drug treatment programs that provide care to HIV-infected drug users.

CONCLUSIONS

We have described five strategies that are widely adopted in programs providing services to HIV-infected drug users. All five strategies aim to address the challenges that HIV-infected drug users face in accessing and utilizing HIV health care services and adhering to antiretroviral therapy. Although various evaluations of different aspects of these strategies have been conducted, rigorous scientific data are lacking. Nevertheless, health care providers and policy makers can draw from a wide range of descriptive information about these services that incorporate many years of program experience and evaluation. It appears that the five strategies discussed above will be among the most important strategies for health care service delivery targeting HIV-infected drug users in the coming years.

We have also described two programs in NYC that focus on different ways to apply one of the strategies discussed above—integration of HIV and drug treatment. These programs highlight the benefits patients' experience with integrated treatment, while also noting continued challenges. The first model, integration of opioid addiction treatment with buprenorphine into HIV primary care settings, has become possible only recently. Thus far, data demonstrate that this integrative model is feasible and can be associated with improvements in health care utilization and clinical outcomes. The second model, integration of comprehensive HIV care services into substance abuse treatment settings, is a more established model that has been better integrated into systems treating HIV-infected drug users. More evaluations of this second integrative model have been conducted, and they demonstrate feasibility, interest, improved health care utilization, and improved health outcomes. Further expansion and refinement of both models of integration has great potential to improve HIV-infected drug users' access, utilization, adherence, and health outcomes.

To move forward in efforts to improve health care for HIV-infected drug users, we will need a better understanding of the different components of each of these unique strategies, research that teases apart the crucial and superfluous components of each strategy, and evaluations that document the specific populations and outcomes that are positively impacted by each strategy. In the meantime, continued creative exploration of these strategies in various settings and populations will advance their development and use and improve health care outcomes among HIV-infected drug users.

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GLOSSARY

The opportunity to receive timely health care services

Adherence to antiretroviral therapy The extent to which an individual takes his/her antiretroviral medications as prescribed

Case management	Assessment, planning, facilitation, and advocacy for options and services to meet individuals' health needs (from the Case Management Society of America, 2007)		
Cognitive behavioral skills techniques	Intervention designed to modify critical cognitions and actions that maintain problem behaviors		
Directly observed therapy	An adherence-improving strategy in which health care providers or program staff directly observe patients taking their medication		
Drug treatment	Treatment of drug abuse or dependence that can include pharmacologic and/or nonpharmacologic treatment, located in inpatient or outpatient settings		
Health care utilization	The extent to which individuals use particular health care services		
Information– motivation–behavior skills model of behavior change	A model of behavior change that asserts that information is necessary but insufficient to alter behavior and that motivation and behavioral skills are critical determinants in promoting behavior change		
Integrated treatment	Treatment that brings together and joins different components of care		
Motivational interviewing	A client-centered yet directive method for increasing motivation for behavior change by exploring and resolving ambivalence		
Outreach	The act of reaching out to individuals to facilitate entering or remaining in treatment		
Peer support	Psychological and/or emotional support provided by a person in a similar social or clinical situation		

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Biographies



Chinazo O. Cunningham, M.D., M.S., is a general internist and Associate Professor of medicine at the Albert Einstein College of Medicine/Montefiore Medical Center. For over 10 years, Dr. Cunningham has been caring for marginalized populations such as HIV-infected individuals, substance users, and the unstably housed. She has developed unique and innovative programs to deliver health care to marginalized populations, along with research and evaluation focusing on their access to and utilization of health care. Dr. Cunningham works closely with community-based organizations and has been the principal investigator on several federally funded grants.



Nancy L. Sohler, Ph.D., M.P.H., is currently faculty at the Sophie Davis School of Biomedical Education of the City University of New York, the Doctoral Program in Public Health at the Graduate Center of the City University of New York, and the Epidemiology and Family and Social Medicine Departments at the Montefiore Medical Center/Albert Einstein College of Medicine. Her research interests include examination of barriers to accessing appropriate health care for underserved populations, evaluation of medical outreach for unstably housed people with HIV and a program which integrates opioid treatment into primary care settings, and examination of how pharmaceutical marketing practices impact health care choices and disparities in treatment for chronic disease such as depression, hypertension, and diabetes.



Nina A. Cooperman, Psy.D., is faculty in the Division of Addiction Psychiatry at the University of Medicine and Dentistry of New Jersey, Robert Wood Johnson Medical School. Her research focuses on HIV risk behavior, adherence to antiretroviral treatment, HIV among women in India, and smoking cessation for drug abusers. She is a member of the Motivational Interviewing Trainers Network, and she often trains health care providers to implement MI to help patients change health-related behaviors.



Karina M. Berg, M.D., M.S., is a faculty member in the Division of General Internal Medicine at the Albert Einstein College of Medicine/Montefiore Medical Center. Dr. Berg's current research interests include optimizing care for HIV-infected drug users. Specifically, she is examining improving antiretroviral adherence and treatment of chronic pain. For her research, she was awarded a Robert Wood Johnson Physician Faculty Scholars Program and a career development award from the NIH. These projects involve combining information from multiple adherence measures through structural equation modeling, examining the agreement and validity of different specific self-report measures of adherence, and exploring the underlying cognitive tasks involved in answering specific adherence questions through qualitative research methods including cognitive interviewing.



Alain H. Litwin, M.D., M.S., is Associate Professor of clinical medicine and psychiatry and behavioral sciences at the Albert Einstein College of Medicine. Since 2000, Dr. Litwin has been providing care in the South Bronx to drug users with complex social, psychiatric, and medical needs within an integrated primary care and MMTP. Dr. Litwin has worked with government and community organizations on community efforts to expand access to hepatitis C virus (HCV) treatment for citizens of NYC. He has worked on policy statements, clinical guidelines, treatment improvement protocols, and educational curricula. Dr. Litwin is currently the Site Principal Investigator of two federally funded programs focused on improving HCV-related care. Dr. Litwin's research has focused on HCV treatment outcomes of methadone-maintained drug users; drug interactions between pegylated interferon and methadone; and HCV-related attitudes, knowledge, and practices of drug users, medical providers, and nonmedical staff. Dr. Litwin currently has an NIH K23 award to study directly observed hepatitis C treatment in methadone clinics.



Julia H. Arnsten, M.D., M.P.H., is a Professor of medicine, epidemiology and population health, and psychiatry and behavioral sciences at the Albert Einstein College of Medicine/ Montefiore Medical Center. Since joining the faculty of the Albert Einstein College of Medicine in 1996, Dr. Arnsten has established an NIH-funded research program focused on adherence to treatment among HIV-infected drug users and on other medical problems affecting substance abusers. In addition, Dr. Arnsten initiated a clinical addiction research and education fellowship for physicians, which has been ongoing since 2002. In 2004, Dr. Arnsten became the Founding Chief of the Unified Division of General Internal Medicine in the Department of Medicine at the Albert Einstein College of Medicine and Montefiore Medical Center. Research in this Division is conducted in a variety of fields, including substance abuse treatment, hepatitis C, tuberculosis, HIV prevention and adherence, nicotine dependence, chronic pain, women's health, medical education, diabetes, and health outcomes.

TABLE 1

A comparison of individuals receiving integrated versus nonintegrated HIV and opioid addiction treatment

	Integrated treatment $(n = 17) n (\%)$		Comparison group $(n = 12) n$ (%)	
	Baseline	6 months	Baseline	6 months
Baseline characteristics				
Age, mean years \pm SD	48 ± 5	-	50 ± 5	-
Male	12 (71)	—	7 (58)	-
Race				
Hispanic	10 (59)	_	5 (42)	-
Black	6 (35)	_	5 (42)	-
Other	1 (6)	_	2 (16)	-
Methadone treatment in past 3 months	5 (29)	_	9 (75)	-
Substance use outcomes (past 30 days)				
Heroin use	16 (94)	6 (35)*	12 (100)	8 (67)
Cocaine use	9 (53)	4 (24)*	7 (58)	4 (33)
Alcohol use	9 (53)	4 (24)*	2 (17)	0
Injection drug use	11 (65)	3 (18)*	9 (75)	1 (8)*
HIV clinical outcomes				
Median CD4 count (cells/mm ³)	348	371	182	140
Median log HIV viral load	8.4	4.8	9.1	9.3
Undetectable HIV viral load	3 (20)	7 (47)	1 (17)	0
Had \geq 1 log decrease in viral load	-	5 (29)	—	0
Health care utilization				
Visits, median	-	8	-	2**
Had \geq 2 CD4 counts conducted	-	9 (53)	-	1(8)***
Other outcomes				
Employed	3 (18)	2 (12)	0	2 (17)
CESD > 16	11 (65)	13 (76)	5 (42)	5 (42)
Good/very good/excellent health status	7 (41)	10 (59)	6(50)	6 (50)

Note: The sample size does not total 27 in every analysis because of some missing data points. CESD = Center for Epidemiologic Studies (Radloff, 1977).

 $p^* < .05$ for within-group differences, using McNemar's test.

p < .05 for between-group differences, using Wilcoxin U-test.

p < .05 for between-group differences, using Fischer's exact test.

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TABLE 2

Baseline characteristics and 3-month follow-up data among 106 individuals enrolled in the STAR Program

	Baseline n (%)	3-month follow-up <i>n</i> (%)
Baseline characteristics		
Male	53 (50.0)	-
Race		
Hispanic	60 (56.6)	_
Black	36 (34.4)	_
Other	10 (9.4)	-
HIV-infected for >3 years	100 (94.3)	-
Medicaid	104 (98.1)	-
Exposure to HIV		
MSM	4 (3.8)	-
IDU	51 (49.0)	-
MSM and IDU	1 (1.0)	-
Sex with intravenous drug user	13 (12.6)	-
Heterosexual sex (other than with intravenous drug user)	22 (21.2)	-
Blood/blood product transfusion	3 (2.9)	-
HIV clinical outcomes		
Median log HIV viral load	3.7	3.2*
Median CD4 count (cells/mm ³)	276.0	275.5
Antiretroviral adherence		
Missed any doses in past 3 days	24 (30.8)	15 (18.5)
Missed any doses in past week	32 (42.1)	23 (28.0)
Well-being in past week		
Depressed	64 (61.0)	51 (51.0)
Everything was an effort	60 (57.7)	59 (59.0)
Difficulty sleeping	73 (69.5)	60 (60.0)
Unhappy	64 (61.0)	52 (52.0)
Lonely	51 (48.6)	41 (41.0)
Didn't enjoy life	47 (45.2)	29 (29.0)*
Sad	78 (74.3)	58 (58.0)*
Could not get going	53 (51.5)	45 (45.0)
Mean number of symptoms of depression (from list above)	5.0	4.0^{*}
Drug use in past 3 months		
Cocaine	35 (33.7)	22 (22.2)
Crack	17 (16.2)	15 (15.0)
Heroin	9 (8.6)	7 (7.0)
Street or club drugs (crystal meth, ecstasy, special k)	4 (3.8)	2 (2.0)
Pain pills or benzodiazepines not prescribed	16 (15.7)	6 (6.0) [*]
Regularly three or more alcoholic drinks a day	17 (16.7)	12 (12.0)

Note: The sample size does not total 106 in every analysis because of some missing data points. MSM = men who have sex with men and IDU = intravenous drug use.

 $^{*}p < .05.$