As the temperatures of summer rise across the country, debate sizzles in public health clinics, physician's offices, bath houses, shooting galleries and places where people living with HIV and their loved ones gather. At the heart of the controversy is the question, "Who should benefit from advances in HIV antiviral therapy?"

At the heart of this question is the ugly notion that patients can and must present themselves as suitable for the "cure." Accompanying the excitement regarding combination therapy has been a whiff of fear based on the assumption that unsuitable patients—most often, substance users—may fail to sustain complex drug regimens and then transmit drug-resistant strains of HIV. While the threat of drug-resistant HIV is real, the identification of substance users as less likely to adhere to medication regimens, on the basis of substance use alone, is unfounded, and the denial of treatment based solely on this assumption is unethical.

This is not to imply that drug use, abuse, or dependence does not increase the chaos in a user's life and surface as a competing demand to adherence. When it becomes a significant contributor to medical decision-making, however, it communicates false information about the potential behavior of an individual and perpetuates the false notion that drug users are acceptable targets for the discrimination that they routinely experience in medical settings. Ultimately, this legitimizes a situation by which scarce resources can be withheld from a group of patients who generally lack ongoing treatment advocacy.

This article looks at the science of resistance and its relation to drug adherence, and the ways in which fears about the failure to comply with combination therapy are misplaced, or more precisely, inappropriately focused on a single group: substance users. Since 1985, researchers have published more than 400 articles on treatment adherence and strategies to enhance it. In general, this literature suggests two conclusions that are central to this article. First, social and psychological supports are critical not only to quality of life but also to adherence, and support services can improve adherence by stabilizing the lives of drug users. Second, it is necessary to research approaches that will enhance adherence among drug users and to expand efforts to advocate for drug treatment.

Exclusion and Epidemiology

The debate about HIV antiviral therapy for drug users presupposes that suitability for treatment can be predicted and uses this predictability as a basis for limiting treatment. The most obvious manifestation of this practice predates triple combination therapy: clinical trials for HIV treatments have traditionally underrepresented women, people of color, and substance users. Several studies have demonstrated significant differences in the availability and use of HIV treatment by race, gender, and injection drug use status.¹

The epidemiology of HIV disease and drug use adds another layer of complexity to HIV treatment access. In the United States and in many industrialized nations, injection drug users entering substance abuse treatment, particularly methadone maintenance programs, have high rates of HIV infection and other infectious diseases. According to the Centers for Disease Control and Prevention (CDC), as of December 31, 1996, 240,000 of the 582,000 people who had been diagnosed with AIDS contract-
Editorial: Drugs and Drugs
Robert Marks, Editor

Last year, a few weeks after returning from the international AIDS conference in Vancouver, I heard Terry Gross interview Marcus Conant on National Public Radio. Conant is one of the pioneers of HIV-related medical care and can always be counted on to challenge conventional thinking.

During the interview, which focused on the success of combination therapy, Gross brought up the issues of treatment adherence, the potential for drug-resistant strains of HIV to form in the wake of non-adherence, and the implications of all of this for drug users with HIV disease. She was merely echoing the general media buzz, which went something like this: while combination therapy was a incredible opportunity for many people with HIV disease, for drug users, it was a dangerous undertaking.

More to the point, non-adherence posed a threat not just to the individual but also to society. And over the past 12 months, some have gone beyond Gross’s not inappropriate curiosity to state that society has an obligation to consider seriously withholding antiviral treatment from drug users.

Conant, who has the largest private HIV medical practice in San Francisco, told Gross that triple combination therapy poses adherence challenges to all people with HIV—substance using or not. A year later, however, adherence is still a hot issue, and drug users continue to be the “population” most clearly associated with these concerns.

Predicting Non-Adherence

In this issue of FOCUS, both physician Andrea Barthwell and outreach worker Luther Brock question the presumption that substance use in and of itself is a predictor of non-adherence. Barthwell, in particular, makes several points that support and expand upon Conant’s assertions.

Three of these points are central: adherence is a challenge not only in HIV-related care, but also in medicine in general (and Barthwell presents some compelling data to prove this point); no one should be excluded from medical treatment based on generalizable characteristics such as drug use; and, finally, when adherence is a problem (and Barthwell recognizes that drug users are both no more and no less likely to adhere) it is medicine’s obligation to find out ways to facilitate adherence rather than to refuse treatment.

Barthwell would be the first to acknowledge that providing adequate substance abuse treatment services—that is, getting people off drugs and into recovery—is a crucial step in ensuring adherence. And she makes some interesting observations about the hidden dangers of harm reduction. But, she emphasizes that it is the doctor’s responsibility, and not the patient’s, to design a treatment plan with the patient’s best interests at its center.

For the mental health professional, all of this may seem a little esoteric. The fact is, however, that there is a good reason adherence is a hot topic: it is a concern for everyone taking antiviral drugs. And it should be one for everyone who supports these individuals, since social and psychological support are critical elements in the effort to help people maintain and sustain the regular use of their medications.

ed HIV in association with injection drug use (their own, a partner’s, or a parent’s). Among those most affected by injection-drug-related HIV disease, and thus by exclusion from treatment, are Hispanics and African-Americans. Hispanics account for 103,000 cases of AIDS (18 percent of the total). Between the years of 1989 and 1994, the percentage of Hispanic cases attributed to injection drug use increased by 127 percent. African-Americans account for 203,000 cases of AIDS (35 percent of the total). African-American men comprise 30 percent of the AIDS cases among men; African-American women represent 54 percent of the AIDS cases among women.

Combination Therapy and Resistance

It is in the context of all of these factors that medical practitioners, drug companies, AIDS advocates, and drug treatment workers have raised questions about the suitability of HIV treatment—in particular, protease inhibitors and other antivirals—for clients who are deemed less likely to adhere, a dangerous process that can lead to discrimination when defining new standards of care.

Non-adherence may occur when a person fails to take an antiviral drug or drugs either at prescribed intervals or dosages, or consistently over the specified period of treatment. If an individual does not comply with a regimen demanded by a particular combination of drugs, he or she may compromise the benefits of treatment, endure potential side effects, and because of the ability of HIV to mutate and develop drug-resistant strains, sacrifice future opportunities to use one or more of the combination’s drugs.

From the time of seroconversion, approximately one-third of the HIV viral population is produced and destroyed each day, resulting in a new population every 14 days and trillions of virions over a period of years.
Even after potent antiviral regimens, chronically infected CD4+ cells contribute to low levels of persistent infection, and while CD4+ production continues over the course of HIV infection, CD4+ counts ultimately fall when production fails to keep pace with destruction. But reverse transcriptase, an enzyme essential to HIV replication, functions with a low degree of accuracy, often leading to mutations—subtle changes in the chemical composition of HIV that can result in a new strain of HIV within an individual. Since the rate of HIV replication is so high, every possible mutation may occur at least once a day. Failure to adhere to a drug regimen may mean that a particular HIV mutation, whose chemical composition makes it resistant to a particular antiviral drug, may proliferate if another drug in a combination cocktail cannot inhibit its replication. Resistance to one drug may lead to the sequential changing of drugs as each fails, and this may result in strains resistant to more than one drug. Adherence becomes a societal concern, because resistant strains of HIV can be transmitted from one vulnerable person to another, and medicine’s capacity to develop new drugs cannot keep pace with the virus’ capacity to mutate.

The Universality of Non-Adherence

The emergence of multi-drug resistant tuberculosis (MDR-TB) as a major health problem (often in people who are HIV-infected) has sensitized health care providers to the issue of drug-resistant HIV. Outbreaks of MDR-TB, however, are related more to serious problems in the U.S. health care infrastructure than to drug adherence itself. While the spectre of drug-resistant tuberculosis feeds fears about potential HIV drug resistance, these fears must not bias the response to people who could benefit from HIV treatment. While biology supports the importance of adherence, its application to decisions about who gets access to care is less defensible because people continue to become infected and to deserve treatment. If adherence is the concern, the medical response must focus on improving it.

After 12 years of research, the clearest finding is that non-adherence is the norm in medical care.

References


Much of the research has focused on the role of health care professionals to detect and respond to non-adherence. These studies have found that—despite the fact that an average of 40 percent of any clinic population fail to adhere to medications—health care professionals, and specifically physicians, often fail to suspect non-compliance. Adherence to drugs in all patient populations, do not communicate clearly what patients need to do to comply, and neglect to establish doctor-patient relationships that motivate adherence. One notable finding was that providers and patients required similar approaches to change behavior in order to improve adherence. Provider behavior was not altered by education and instruction alone; it required performance audits and feedback, apprenticeship programs, and training, all difficult but necessary tactics. While studies have found that patient adherence is largely unrelated to socioeconomic status and education, is not a matter of simply obeying instructions, and is related to a variety of factors, the research does not fully explore the active role patients may play in consciously choosing not to adhere. Seeking to make rational decisions about treatment, individuals naturally perform risk-benefit analyses, taking into account, for example, beliefs about the effectiveness of medications, the severity of side effects, and the difficulty of regimens. In particular, according to the research, adherence is related to what patients feel they can carry out. For instance, in response to difficult side effects, some patients will take lower doses. To handle drug-related nausea that prohibits them from eating, others may reduce or eliminate doses taken with meals. Finally, some parents will reduce the number of pills they give their children when they attribute new complaints to the effects of the medication or when they have to fight with the child to take the dose.

Research has validated a number of strategies to improve adherence. Compliance with treatments of less than two weeks can be improved by the provision of clear instructions, the use of special pill containers and calendars, and the development of simpler medication regimens and non-oral routes of administration. Long-term adherence is more difficult, and no single intervention has proven to be self-sustaining or useful on its own. Improvement usually requires a combination of three or more approaches.
The most successful interventions for long-term adherence involve cues and rewards such as coupons to purchase goods. But approaches like these are labor intensive and impractical in medical clinic settings, although health educators or allied health practitioners may be able to apply them in other settings. Counseling, support groups, and home visits can deliver the social support that seems to enhance compliance; in one hypertension study, a combination of group discussion and supervised self-management proved helpful in sustaining adherence. Another study found that contingency contracting—linking consequences to adherence—was useful in shaping behavior change. For example, sending a letter to a significant person in the patient’s life when the patient complied imparted positive reinforcement. However, as another study found, patients may not select the contingency contracting option if failure to comply leads to negative consequences.

The bottom line is that none of the research makes distinctions between drug users and non-users that are significant enough to justify excluding users from treatment. In fact, since much of the research focuses on general clinic populations, researchers have applied their results to both users and non-users.

**Harm Reduction and Adherence**

To improve adherence among drug users as among all others, practitioners must seek to understand their patients’ belief systems, deliver accurate information to influence beliefs, and in cases when competing demands are compelling, help to reduce distractions. For drug users, the chief distraction is substance use itself or the avoidance of withdrawal, which becomes the organizing principle of most addicts’ lives. The spectrum of drug use ranges from “incidental” to “cardinal.” Most people have probably experienced incidental, or non-medical, use of at least one mood- or mind-altering chemical, and incidental users with HIV disease are able to attend to the demands of antiviral treatment. Cardinal use, however, results in an allegiance to drug use so strong that it becomes the primary force in a user’s life. The distinction between the extremes of this spectrum is marked, but in an era of harm reduction, it has become blurred.

When applied to drug users at the severe end of the continuum, harm reduction—which theoretically enables HIV-infected drug users to continue using while receiving medical care—may do just the opposite. Instead, it may offer a deceptive opportunity both to remain “well” and to continue drug use, when in fact, for many users, drug use actually interferes with adherence and foils medical care. In this way, harm reduction offers a kind of minimalist care: HIV care, but no drug-related treatment, social services, or social support.

**Conclusion**

The response, however, is not to do away with medical care for active drug users but, on the contrary, to enhance it. Drug use is one small piece of the non-adherence puzzle; the largest piece is the way in which providers reach out to patients and deliver health care. Instead of further excluding populations that do not match established templates, health practitioners need to develop models of medical and mental health service that match the lives of the variety of people they treat. The first step is to recognize that research has not uncovered a way to predict who will or will not adhere to HIV therapies. Only after realizing this can we move beyond -isms and generic judgments and make available the exciting new treatments at our disposal to the full spectrum of people with HIV disease.

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**Clearinghouse: Drugs and Adherence**

**References**


East Palo Alto is a strong California community of 25,000 residents located between San Francisco and San Jose. A city of two square miles in size, this community is nestled in the South Bay near the corridor between San Mateo and Santa Clara counties. It is predominately comprised of African-Americans, with a growing number of Latino and Asian/Pacific Islander residents.

Several years ago this community was referred to as the homicide capitol of the United States. A recent study found that East Palo Alto had the largest number of HIV-infected African-American injection drug users per capita of any city west of the Mississippi. A significant number of HIV-infected individuals from this community are drug addicts and alcoholics, and many are in or are seeking rehabilitation so that they can return to work and become productive members of the community.

A Community Care Partnership

What doctor makes house calls in this day and age? Well, there is one who still does—sort of. Dr. Dennis Israelski, a physician and a researcher, has shown a commitment to his patients that is seldom seen in this age of managed care. When they miss appointments to see him, he finds them through an informal network of care providers, social workers, case managers, and drug recovery counselors. He knows if they have missed appointments for detoxification. He knows if they are back on heroin or crack. If they are homeless, he will meet them on their own turf, whether it’s on the street, under a bridge, or in the bushes. His patients see him in the community—he works on task forces, speaks at town meetings, and drops in to support groups—and they know that he cares about them and because of this, that he is a presence to be reckoned with.

When I first met Dr. Israelski, he asked me how I felt about giving practicing drug addicts the new protease inhibitors, specifically indinavir (Crixivan). We talked about the scientific community’s concerns about the potential emergence of drug-resistant strains of HIV if an individual did not adhere to the demanding combination treatment regimens. My response was clear. During the previous year, I had attended the funerals of 14 HIV-positive friends, many of whom were practicing addicts. It was unmistakable to me that addiction killed them more quickly than HIV infection. Many had started antiviral drug therapy too late; some did not even have a primary care physician.

Treatment Stories

Rob, a recovering drug addict with HIV disease, needed morphine to stop the pain of HIV-related peripheral neuropathy. But Rob was concerned that morphine treatment might jeopardize his recovery from drugs. He feared that if he ran out of morphine in the middle of the night, he would go to the streets to find heroin. Because I am not HIV-positive, it took Rob some time to trust me. He didn’t feel that I was “qualified” to fully understand his plight. However, as a recovering drug addict
myself, I had walked many miles in his shoes and was able to gain his confidence on familiar turf. I talked to other HIV-positive addicts who maintained sobriety while using morphine to manage pain. It was by providing this link to others who had dealt with similar experiences and fears and to information that I won Rob’s trust and helped him live clean, sober and pain-free.

Louis’s alcohol and drug addiction repeatedly interfered with attempts to respond to the wasting syndrome, *Pneumocystis carinii* pneumonia (PCP), and esophageal candidiasis he was battling. Dr. Israelski told Louis that none of his patients who continued to use drugs lasted long, pleading, “I can help you get healthy, but I need your help.” At Dr. Israelski’s request, I gave Louis a stark choice: either go to a hospice or get into outpatient residential drug treatment and start aggressive combination antiviral and antibiotic therapy. But, Louis began using again and this affected his ability to comply with treatment.

Through the efforts of a team of drug recovery counselors, social workers, nurses, and physician assistants, Louis had a breakthrough. He got into a methadone program and was able to adhere to his treatment regimen. Today, Louis is part of a strong supportive network of HIV-positive, clean and sober addicts. He has two jobs and lives with his partner and two children. He has gained more than 100 pounds, increased his CD4+ cell count to 155, and reduced his viral load to below detectable levels.

Carla had already lost a family member to AIDS, and it took her some time to see that it was possible to live with HIV disease. Carla had more than her share of medical problems: she had been on dialysis as a result of drug addiction, had developed progressive multifocal leukoencephalopathy (PML), had a minor stroke, and been told she had six months to live. It seemed as though the moment she knew the odds were against her, Carla found renewed strength. She began taking her medications, got plenty of rest, and learned about ways to respond to her opportunistic infections. Once she took action, she became more optimistic, and began to look, sound, and feel better.

**Walking Together**

In the course of my community education and outreach efforts, Dr. Israelski and I work closely, talking several times a week. We discuss the status of our mutual clients and strategies to address problems such as missed appointments, medical emergencies, and housing needs. Some patients require detoxification or a referral for drug treatment. Some require help intervening with the criminal justice or court systems. Some need psychotherapy. Many are eligible for enrollment into HIV drug clinical trials.

We’re not always successful. For example, Joe promised he’d go into outpatient drug treatment, but his significant other and most of his friends were still using drugs. Even though I made a pact to support him throughout his recovery—ensuring that he stay in touch with his case manager, attend support groups, and keep with the drug treatment program—Joe relapsed. He died having chosen the temporary euphoria of crack and heroin addiction over life.

But, often we are successful, and when we are, it’s because we communicate a few basic messages: HIV disease and substance use form a lethal combination. To fight HIV, learn about your CD4+ cell counts, viral load levels, opportunistic infections, and medications. Get involved in your health care. Keep your care providers in the loop.

Many recovering addicts refer to their drug days as being “in the life.” That “life” is harsh, fast-paced, unpredictable, and rebellious. When I was in the life, I used to view the system of parole officers, social workers, and case managers as the “man”: the establishment, people who were trying to take away my “high.” I never fully understood that many of these people actually cared about me. Now that I’m on the other side, I see myself in the faces of my clients. I realize that I would not be here if people had not cared about me. And I realize that this is a crucial message behind the success stories of Rob, Louis, and Carla. Fortunately, there are a growing number of people who can and are willing to help drug users live more healthy and productive lives, and to deal with the complexity of the new treatments. And, as drug users with HIV disease do better, their success attracts others who feel as hopeless as they once did.

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**Comments and Submissions**

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Recent Reports

Drug Use, Psychiatric Illness, and Adherence

A small retrospective study of HIV-infected injection drug users in methadone maintenance treatment found no correlation between adherence to zidovudine (ZDV; AZT) treatment and recent illicit drug use. The study did find that the need for psychiatric consultation or follow-up predicted reduced adherence. This data suggests that adherence problems among drug users reported in previous studies may be related to psychiatric illness and not substance abuse in and of itself.

Researchers performed a retrospective chart review of 57 HIV-infected injection drug users in a San Francisco methadone maintenance treatment. Of these, 46 (81 percent) required psychiatric consultation or follow-up. Adherence to ZDV during the four month period of study was determined by measuring the change in mean corpuscular volume (MCV), since MCV characteristically rises in the majority of patients on ZDV at least two weeks after beginning treatment. Illicit drug use was quantified by calculating the percentage of drug-positive urine tests: there was no significant difference in levels of illicit drug use between the group of subjects who needed psychiatric consultation and those who did not. Subjects required psychiatric consultation for conditions including substance dependence disorders, mood disorders, organic mental syndromes, and adjustment disorders.

As a whole, compared to the group that did not require psychiatric consultation and follow-up, the group that did undergo consultation had lower increases in MCV levels of ZDV and a smaller percentage of subjects with MCV levels greater than 100, indicating lower compliance. These relationships changed, however, when subjects were divided into diagnostic categories: the MCV values of subjects with depressive disorders or with substance dependence disorders did not differ when compared to all the subjects in the non-psychiatric evaluation group.

Among the study’s limitations were its small sample size, the fact that researchers based psychiatric diagnosis on retrospective chart review and not on standardized diagnostic indicators, and the assumption that individuals in the non-psychiatric consultation group were without psychopathology. In addition, poor adherence to HIV medications may indirectly produce psychiatric morbidity and cognitive impairment by increasing the susceptibility to central nervous system infections or HIV-associated dementia. In addition, ZDV can cause symptoms such as depression and anxiety; thus, it is conceivable that ZDV use may in and of itself contribute to poor adherence.

Supervised Treatment to Promote Adherence


Two studies of injection drug users assert that interaction with care providers during the course of treatment improves medication compliance for HIV disease and tuberculosis, respectively. Both studies—one using “supervised therapy,” the other discussing “directly observed therapy”—suggested that social support is a significant factor in maximizing adherence to difficult treatment regimens.

Researchers in the first study followed 25 HIV-infected drug users who were undergoing methadone treatment in San Francisco. Subjects of the study were randomly selected from a list of HIV-infected methadone maintenance patients who were taking ZDV. Out of the subject pool, researchers targeted those patients who reported having lower levels of treatment adherence. During the course of the study, researchers monitored adherence using four different measures: self-report, mean corpuscular volume (MCV) of medication, pill counts, and a score derived from a Medication Event Monitoring System.

Nurses carried out “supervised therapy,” dispensing daily medication, providing take-home dosages of ZDV, counting pills remaining from prior dosages, inquiring about adherence to treatment and about associated adverse side affects, and providing feedback about CD4+ levels and MCV results. Researchers compared clients under supervised care with a group of HIV-infected injection drug users

Social support is a significant factor in maximizing adherence.
receiving unsupervised treatment: these subjects received information about ZDV at the onset of treatment but had limited future contact with medical staff.

Compared to those in the unsupervised group, subjects who were supervised showed statistically significant improvements in adherence as measured by MCV levels. This finding was supported by nonsignificant trends in self-report, MEMS score, and pill count. These improvements, however, were short-lived: adherence levels dropped off on the weekends when no supervision was provided, and one month after supervised treatment had ended, there were no significant differences in adherence between subjects in supervised and unsupervised groups. Despite the failure to sustain adherence, the study demonstrated the importance of ongoing social support in ensuring effective treatment among drug users, a notable finding in light of the fact that injection drug users have the highest drop-out rate from ZDV clinical trials.

The second study examined the implications of directly observed therapy among injection drug users with tuberculosis. Researchers conducted 210 ethnographic interviews with 68 drug users in places such as shooting galleries, crack houses, and abandoned buildings in Brooklyn, New York. They paid subjects $10.00 and tape-recorded the interviews. Of the subjects, 67 percent were women; 41 percent were Latino, 32 percent were Black, and 26 percent were White; 85 percent smoked crack cocaine (many “infrequently”); and 68 percent had been injecting drugs for an average of 13 years.

Subjects reported that many New York hospitals were reluctant to admit injection drug users because users are considered to be “difficult and expensive” patients to treat. Subjects said they avoided TB diagnosis and treatment, drug treatment, and AIDS outreach workers because they feared TB-related involuntary detention. Further, subjects reported leaving hospitals before receiving TB treatment because of a perceived lack of respectful treatment and understanding, or because of a lack of adequate methadone therapy.

Earlier research suggests that directly observed therapy (DOT) is a relatively affordable method of TB control. As with supervised therapy, DOT involves direct observation and recording of each dose of medication. While DOT studies have had limited success, there is reason to believe that, added to other types of drug treatment such as methadone maintenance, DOT would prove to be more effective.

Non-Adherence and Injection Drug Use

Non-adherence with zidovudine (ZDV; AZT) treatment regimens may be routine among injection drug users, according to a review of the literature on this topic and ethnographic interviews with 10 male injection drug users in New Jersey.

Some reasons for non-adherence reflect everyday struggles. For example, some injection drug users hoarded ZDV in order to sell it, give it away, or stock it for future use were they to become sick. Other reasons for noncompliance were closely linked to drug use itself: forgetfulness, confusion about the ZDV regimen, and fear of overdosing, for example, from a mix of ZDV and street drugs. Injection drug users also had a tendency to self-adjust their ZDV regimens based on “addict folklore.” Finally, drug users said they took lower doses of ZDV because they said it “held them,” which suggests that they view the effects of medication much as they view a “fix” of heroin (which wards off the effects of withdrawal). Approaches to improve adherence include using pill calendars; offering drug users clear, oral instructions; increasing supervision; and packaging ZDV in ways that facilitate compliance with drug regimens. However, systemic changes may be needed to mitigate barriers to adherence.

Next Month
Seropositive people with mental illness pose challenges to providers that extend well beyond the already complex issues faced by most people with HIV infection. These clients rarely appear in newspaper articles, but show up, often in crisis, at HIV clinics. In the September 1997 issue of FOCUS, psychiatrist George Harrison, MD, Medical Director of the AIDS Health Project’s Psychiatric Consultation Program, offers a glimpse into the day-to-day workings of a psychiatric crisis intervention team.

Also in September, John D. Harbison, MD, Medical Director of the partial hospitalization program at San Francisco General Hospital, discusses the treatment of people with both HIV disease and chronic mental illness.
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