When the era of highly active antiretroviral therapy (HAART) began, treatment strategy seemed simple: get everyone who could tolerate it onto HIV antiviral regimens as soon as possible. In the six years since, resistance and toxicity problems have made both providers and patients more cautious about treatment, even as medication options expand and regimens simplify. We are exploring the limits of the new technology: what are the lowest doses that will work, how long can treatment be delayed and still prevent serious consequences of the illness, and what is the best way to avoid resistance and long-term side effects?

Balancing Treatment Burdens and Benefits

The data confirm that people whose CD4+ cell counts are less than 200 should start on and stay on HAART. Treatment in this group is unequivocally life-saving. For people with CD4+ cell counts above 200, there is good theoretical support both for treating early in disease—CD4+ cell counts of between 350 and 500—and for delaying therapy until levels fall below 350, or even just above 200. The arguments for early therapy focus on three factors: the fear that irreparable damage to the immune system may occur while therapy is delayed; the evidence that control of viral replication is easier when treatment starts earlier in the course of disease; and the hope that lowering viral load may help prevent transmission to others. The arguments for delaying therapy raise other concerns: the drugs have unknown long-term toxicities that may offset the benefits of therapy; less drug exposure means less drug-resistant virus; and taking the medications reduces quality of life and should be delayed if treatment cannot be proved to be helpful.

In the early days of HAART, opinion firmly supported early treatment, advocating the "Hit early, hit hard" approach. More recently, growing concerns about lipid and glucose abnormalities, body shape changes, and bone density loss have encouraged a shift toward the delayed treatment strategy, as has the experience of some individuals on early treatment, who churned through multiple regimens in only a few years, leaving them with multidrug resistant virus and limited treatment options for the future. Both of the bodies that promulgate treatment guidelines in the United States (the U.S. Department of Health and Human Services and the International AIDS Society–USA) have in the past two years backed off recommendations for early treatment in favor of delaying therapy until CD4+ cell counts fall to 350 or less.

Whether 350 is the right cut-off for initiating therapy will take years to confirm and require large-scale randomized trials. Current data from retrospective reviews offer conflicting answers, as is clear from two examples. The Swiss HIV Cohort Study was a case control study of 716 patients with CD4+ cell counts less than 350, half of whom started HAART and half of whom delayed HAART. After two years, 4 percent of the early starters had developed symptoms of HIV disease versus 17 percent of the delayers, and all-cause mortality rates were significantly lower for the early starters than for the delayers (1 percent versus 5 percent). On the other hand, a Johns Hopkins University study of 1,014 patients found no difference in clinical disease progression when treatment was started at CD4+ cell counts of between 201 and 350 compared to when treatment was delayed until counts fell to under 200.

Strategic Treatment Interruptions

Strategic treatment interruption (STI) is another tactic for limiting lifetime exposure
Editorial: Counseling the Physician
Robert Marks, Editor

The HIV epidemic has been one of the most potent forces over the past 20 years connecting physical health care to psychology. On a practical level, we have come to appreciate both the psychosocial impact of HIV treatment challenges and decision making on mental health, and the medical impact of psychological factors on treatment adherence and HIV disease prevention.

These impacts have required mental health providers to understand the medical treatment issues that their clients face and medical providers to consider the emotional content of HIV prevention and care. In particular, they have highlighted the role of medical providers in counseling, in addition to “treating,” their patients. In this issue of FOCUS, Kathleen Clanon responds to the first of these impacts by updating readers on the most unsettled areas of HIV treatment; Janet Tobacman responds to the second by describing the role of health care workers in HIV counseling.

There is little controversy among mental health practitioners regarding the value of being informed about HIV-related medical topics. It is rarely necessary for therapists or support group facilitators to disseminate medical information—and, obviously, inappropriate for them to make medical recommendations. Most health professionals nonetheless recognize the role mental health workers play in helping individuals resolve psychosocial barriers to treatment adherence and uncertainties about treatment decisions. An overview of current medical issues like the one that Clanon offers ensures that mental health providers understand the general context in which their clients reside.

Among too many medical providers and insurers, there is less support for the concept that physicians can and should play an active role in preventive care. With HIV disease, however, the need for this involvement is growing in light of increasing HIV infection and ever-changing HIV treatment. Most of the HIV antibody testing in the United States is performed in private medical care settings, but much of it occurs without any significant exploration of a patient’s risks before results disclosure and little follow-up discussion after disclosure—even for HIV-positive individuals who might be expected to enter ongoing medical care.

Of course, the underlying problems—the unwillingness of health insurers in the United States to embrace preventive care and the failure of many medical providers to accept the central role of psychology in treatment—seem intractable. Improving them requires more leadership than so far has been mustered. Nonetheless, Tobacman offers some insights into the problem and some straightforward ways through which the situation might be improved. If applied broadly, front-line provider by front-line provider, these small steps may evolve into a powerful antidote to institutional malaise, significantly contributing to the goals of HIV prevention and care.

to HIV antiviral drugs that is now under intense investigation. Studies of the immune function of people who are long-term HIV non-progressors show that the T cell system can be effective for years in controlling the virus, if this system survives the initial stages of HIV illness. The theory behind treatment interruption is first, to use an antiviral regimen to suppress HIV infection in order to allow the immune system to restore itself, and then to stop treatment and “re-expose” the strengthened immune system to HIV. Theoretically, this “teaches” cytotoxic T lymphocytes—white blood cells that kill invaders like viruses—to recognize and target HIV, thereby eliminating the need for continued long-term use of HIV antiviral medications.

In a cohort of 11 patients who, immediately after seroconversion, went through four cycles on and off therapy, after one year, three were maintaining very low or undetectable viral load off drug and seven showed improved cytotoxic T lymphocyte response.3 Unfortunately, the news is not so encouraging among the chronically infected. The Swiss-Spanish Intermittent Treatment Trial, a randomized, controlled trial of STI in 133 chronically infected people, has found no consistent increase in cytotoxic T lymphocyte function after 96 weeks and four STI cycles. Only 11 percent of participants sustained viral control during the interruptions. Finally, in those with late-stage HIV and CD4+ cell counts of less than 200, STI is outright dangerous. The EuroSIDA study found the risk of new opportunistic infections to be 2.4 times higher among patients who interrupted HAART than among those with the same CD4+ cell levels who stayed on treatment.

References
HIV Medication Resistance

One of the primary reasons for caution in the use of HIV antiviral treatment is the potential for a person’s HIV to become resistant to a particular antiviral drug or drugs. Typical U.S. studies show that 50 percent of people will have virologic failure of their first medication regimen within one year of initiation, most often due to development of resistance. Providers tend to approach the problem of resistance in one of two ways. “Sequencers” assume resistance is inevitable and favor initial regimens designed to preserve future options by using those drugs that are more likely to lead to resistance later in the treatment process. “Simplifiers” seek to prevent resistance by facilitating adherence, and favor starting with the simplest regimens regardless of sequencing considerations.

Concerns related to both sequencing and simplification play a part in every HIV treatment decision, but the choice of emphasis can result in very different prescription practices. For instance, simplifiers might use zidovudine/lamivudine (Combivir) and efavirenz (Sustiva) as an initial regimen in a treatment-naive patient, because it has a low pill count (three per day) and less bothersome side effects but retains high potency to inhibit HIV. A sequencer might start the same patient on a protease inhibitor-containing regimen, preserving the non-nucleoside reverse transcriptase inhibitor (nNRTI) class, in this example efavirenz, for a later salvage strategy.

Resistance clearly has a big impact on the likelihood of treatment success and therefore on health, however, the popular image of the mutant supergerm has not been borne out. Drug-resistant virus is not stronger virus; for example, mutations associated with nucleoside reverse transcriptase inhibitor resistance in some cases increase HIV’s vulnerability to the non-nucleoside class of drugs (“hypersusceptibility”). In addition, mutations in essential viral genes, while allowing for resistance to one drug, also may impair the ability of the virus to replicate and to cause disease (“reduced fitness.”) More evidence for this effect is found in the observation that late in illness, people have fewer opportunistic infections if they remain on HAART than if they go off, even if their viral load is high because of extensive drug resistance. This suggests that the virus they have while on drugs is less able to impair immune function than the “wild-type virus” that would be found to reemerge in someone who discontinued drugs.

Having said this, resistance is an increasingly troubling problem. Supergerms or not, resistant virus makes treatment more complex and less successful. One particularly worrisome problem is the transmission of drug-resistant virus to newly infected people. In a retrospective review of 337 people who presented with primary HIV illness between 1995–2000 in 10 North American cities, researchers reported that the frequency of high-level drug resistance in these drug-naive patients increased over time from 3.4 percent in 1995–1998 to 12.4 percent in 1999–2000. They also noted that those patients who acquired resistant virus had less success with HAART than those who did not, demonstrated by poorer viral suppression rates and shorter time to first regimen failure.

Now that the transmission of drug-resistant virus from one human to another has been documented, the question of whether or not “superinfection” occurs becomes more pressing. There has been an ongoing debate for some years as to whether people already infected with one strain of the virus can be reinfected with a new strain and whether this “double whammy” would have an impact on the course of the illness. A case presented at the XIV International Conference on AIDS in Barcelona appears to prove conclusively that the phenomenon does occur. A Swiss man initially infected with the clade A/E virus, a specific strain of HIV, lost viral control after a treatment interruption. He was subsequently discovered to also be infected with a particular subtype of clade B virus not common in Switzerland, but very common in Brazil, where he had recently vacationed and had unprotected sex. Superinfection with a multi-drug resistant virus would be a disaster in someone who had few HIV treatment options left.

Keeping Ahead of the Virus

Work is being done with currently approved drugs and new medications in the old drug classes to make adherence easier and resistance more difficult for the virus to
achieve. Work horse drugs didanosine (ddI), lamivudine (3TC), efavirenz (Sustiva) and tenofovir (Viread) are all now approved in the United States for once-a-day dosing, and data support the use of several boosted protease inhibitor regimens once a day. Even zidovudine (ZDV; AZT), which clinicians once insisted on dosing every four hours, is now being studied as a once-daily drug. A new once-a-day protease inhibitor, atazanavir, will likely be approved later this year. It has the additional advantage of avoiding the deleterious effects on lipids that are seen with most other protease inhibitors. Several new nNRTIs (for instance DPC083 and capravirine) that are effective against viruses with the K103N mutation are in development; when this mutation occurs, it renders the whole current nNRTI class virtually useless.

For the first time in several years, whole new classes of agents—fusion inhibitors and integrase inhibitors—are nearing approval. This is particularly exciting for people who have run out of current options because of drug resistance. One new class, the fusion inhibitors, undermines the mechanism that allows the virus to enter uninfected cells, making it likely to be the first approved HIV medication that interferes with the virus outside host cells. A Barcelona presentation reported on clinical trials in highly-HAART-experienced subjects using either a HAART regimen alone or the HAART regimen plus the fusion inhibitor T-20 (enfuvirtide). After 24 weeks, the T-20 arm showed a remarkable decrease in viral load when compared to the control group. One cautionary note is that when used alone as monotherapy, T-20 can lead to resistance within weeks.

Integrase inhibitors hinder the entry of HIV viral DNA into host-cell chromosomes. According to a Barcelona presentation on the first human trials of one integrase inhibitor, S1360, although resistance mutations have already been seen in vitro, the drug has a distinct resistance pattern. This allows it to be used against viral strains resistant to all currently licensed HIV antiviral drugs, making it another exciting possibility for people with few or no treatment options left.

The complexity of HIV treatment, and particularly of antiviral therapy, has brought additional attention to the question of who should be prescribing these drugs. It now seems clear that it is possible for medical providers to make mistakes that, by facilitating the development of pan-resistant virus, could shut a patient out from life-prolonging therapy. HIV expertise exists, and its impact on patient outcomes has been documented, but there is not yet a nationally accepted certification process for HIV experts. This year, California became the first state to address this situation by enacting a law requiring health maintenance organizations to make HIV expert physician consultation available to their members.

Conclusion

Although resistance and drug toxicity are frequent and serious for people on HIV antiviral treatment, they have not so far reversed the overall gains in survival achieved since the first years of HAART. While there have been no revolutionary developments in HIV treatment since the late 1990s, medicine has been able to keep just ahead of the virus through the smarter use of existing agents and the development of new agents. We can only hope our ingenuity will continue to outpace that of our adversary.

References


HIV Testing and Counseling in Adult Primary Care Settings
Janet Tobacman, MPA

Most people in the United States who get tested for HIV do so in their physicians’ offices. Indeed, targeted HIV testing and counseling in primary care settings is an important HIV and sexually transmitted disease (STD) prevention strategy. In addition, these visits are an ideal time to test patients with indicators of possible HIV infection, and in doing so, expedite HIV specialty care and reduce the further spread of HIV disease. Unfortunately, these opportunities for HIV counseling, testing, and referral are often missed, particularly in some private medical settings. Imagine these two common scenarios.

Scenario 1: A patient visits her doctor complaining of a backache. The doctor treats her for pain and is about to leave the room when the patient asks for an HIV test. The doctor is rushed and assumes that his middle-class married patient is not at risk for HIV. He recommends against the test.

Scenario 2: It’s flu season. A patient comes in with a sore throat and fever. The physician sends the patient home with instructions to rest and drink plenty of fluids. When the patient is admitted to the hospital a year later, tests reveal he is HIV-positive.

In both of these cases, physicians made assumptions about their patients, or lacked the skills or support to properly assess or counsel their patients about HIV-related risk. In each case, the opportunity to provide prevention or early intervention was lost.

In its most recent Counseling, Testing, and Referral Guidelines, the Centers for Disease Control and Prevention acknowledged that while private sector primary care providers should make HIV testing and counseling available, the approach used at public test sites may be too time-consuming or may not match the needs of patients seeking general health care services. There are many creative strategies, however, that can be used in these settings to meet patient needs without unduly burdening physicians.

Talking about STD Risk

In 2000, findings from the U.S. National Health Interview Survey (NHIS) defined the STD testing challenge. The study found that of 3,390 adults aged 18 to 64 who reported having a routine medical checkup in 1994, only 28 percent were asked about STDs during the visit. On the other hand, 59 percent were asked about smoking. It is good that Advise to Quit programs have raised awareness about smoking cessation. But why are providers not asking about STD risks? Why is there no Ask About STD Risks campaign?

Studies implicate a variety of factors that influence the nature of doctor-patient interaction regarding STD and HIV risk, including limited time, lack of adequate training, and perceived lack of patient interest. How can these challenges be overcome?

Some studies indicate that patients want their doctors to bring up the issue of STDs, yet many providers think their patients would be uncomfortable with antiretroviral drugs in 81 individuals newly infected by sexual contact or injecting drug use. AIDS. 2000; 14(2): F17–F23.

Selwyn PA. Prospects for improvement in physicians’ communication skills and in prevention of HIV infection. The Lancet. 1998; 352(9127): 506.


See also references cited in articles in this issue.
questions about sexual practices. Given these divergent perspectives on the sensitive topics of sex and sexuality, how can primary health care settings, particularly in the private sector, better support open discussions between patients and providers about STD and HIV risk?

Some health care organizations have bypassed the issue of physician comfort level and time constraints by taking an approach similar to many publicly funded HIV and STD clinics. Non-physician staff—including nurses, health educators, and social workers—are trained to provide client-centered HIV and STD test counseling. Staff in these settings are likely to have ongoing relationships with clients, which means that sexual risk can be addressed over time and in the context of a client’s overall health. This process is enhanced by the fact that staff may have access to a client’s medical chart, increasing the potential for the session to go beyond a generic interaction toward a more client-centered one.

Still, some patients in primary care settings have come to see a doctor, and it is a doctor with whom they want to talk. Medical training for internists generally includes little on communicating with patients about sexual issues, or for that matter, other subjects such as death and dying, illegal substance use, and domestic violence. One approach to this barrier might be to offer primary care providers training on how to address the variety of these sensitive topics.

In busy primary care settings, systems can sometimes be implemented to prompt providers who may miss prevention opportunities due to time pressures. Lab requisitions for STDs can cue providers to consider HIV testing, and vice versa. General risk assessment forms can include questions about STDs and HIV along with those about smoking, exercise, and nutrition. Such forms may also contain questions asking patients whether they would like to discuss any of these issues in greater depth during the appointment. If a provider knows at the outset that a patient has particular concerns, the provider can more easily structure the appointment to address those concerns.

Earlier Detection and Prevention

Patients might also benefit from greater provider awareness in terms of early HIV detection. Studies of patients in a variety of public and private settings indicate that 40 percent to 50 percent of people diagnosed with HIV in the United States already meet a clinical definition of AIDS.5,6 Commonly missed indicators that could trigger earlier testing or diagnosis include community-acquired pneumonia, herpes zoster, unexplained fevers, unexplained weight loss, and genital or oral STD infection. To increase the likelihood of testing in primary care settings, it may be useful for HIV specialists to encourage awareness among their primary care colleagues. It may also be useful for private, public, and community-based providers to work collectively to identify strategies that reduce HIV testing-related stigma for both providers and patients. The remedy for this might include communication and AIDS education training for providers as well as ongoing public awareness and community outreach efforts.

One national study found that 23 percent of people diagnosed with HIV at a time when their immune systems were already severely compromised had previously tested HIV-negative within the prior five years.7 The fact that there was advanced immune decline suggests that some of these individuals may have been HIV-positive for several years. The fact that many had tested before suggests that they may have been aware of ongoing risk. Earlier re-testing and client-centered counseling at the time of earlier testing might have provided opportunities to uncover risk, develop risk reduction strategies, and offer timely specialty care for people who tested HIV-positive. Such counseling might have been facilitated by systems that allow for frank conversations about HIV risk.

Conclusion

Communication about sex, HIV, and STDs is often limited by discomfort among both providers and patients and by time and systems limitations. Creative solutions can help medical care professionals provide counseling within these constraints, thereby reducing HIV risks and improving HIV care.

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Recent Reports

Superinfection and Recombination
Blackard JT, Cohen DE, Mayer KH. Human immunodeficiency virus superinfection and recombination: Current state of knowledge and potential clinical consequences. Clinical Infectious Diseases. 2002; 34(8): 1108–1114. (Fenway Community Health, Boston; and Brown University.)

A review of published literature concerning HIV superinfection and recombination estimates the number of HIV infections that are caused by recombinant viruses could be around 10 percent worldwide and might be as high as 20 percent in some nations. Recombination may contribute to the production of treatment-resistant strains of HIV, and may alter viral pathogenicity, accelerate HIV disease progression, and undermine the efficacy of current HIV diagnostic tests.

Superinfection, a necessary precursor to recombination, is the infection of an individual with two or more genetically distinct strains of the HIV virus. Superinfection can occur in a single transmission event—from an individual with more than one strain—or from multiple events. Recombination occurs when the error-prone reverse transcriptase enzyme—the enzyme HIV uses to replicate its genetic material—uses genetic sequences from more than one strain, the result being a new "recombinant" strain.

Laboratory research has shown that recombination can occur within two weeks of infection and that HIV-1 undergoes recombination two to three times per replication cycle. Other researchers have shown that HIV-infected cells within a superinfected individual are usually multiply infected, and they have estimated that 6 percent to 18 percent of viruses produced in these cells are recombinant strains.

Increase in Drug-Resistant HIV Strains

Treatment-resistant HIV increased from 3.4 percent to 12.4 percent, according to a study that compared people newly infected with HIV during the period 1995–1998 with those newly infected during 1999–2000. Individuals identified with resistant strains also underwent a longer period of time to achieve viral suppression.

Researchers recruited 377 study participants from Acute Infection and Early Disease Research Programs in 10 North American cities. Participants had to have seroconverted within the previous 12 months or displayed evidence of acute or early HIV infection, and not taken HIV antiviral treatment for more than seven days. Of the participants, 91 percent were men, and 72 percent were White, 16 percent were Black, and 10 percent were Hispanic. The average age of the sample was 35 years. Subjects received one or more antiviral drugs.

Researchers calculated the time to viral suppression and, using nucleotide sequence analysis, detected well-known drug resistance mutations of the HIV pol gene. Resistant HIV strains were defined by comparing the amount of each drug required to decrease viral load by 50 percent to the amount required to inhibit a drug-sensitive reference strain by 50 percent.

Genotypic analysis of blood samples revealed that the presence of mutations resistant to any single drug increased significantly from 8.0 percent for the period 1995–1998 to 22.7 percent for the period 1999–2000. The analysis also found resistance to multiple classes of drugs increased from 3.8 percent to 10.2 percent over the same time. The magnitude of this change was mirrored in the viral response to treatment of subjects: 1.1 percent of subjects from the 1995–1998 period experienced resistance compared to 6.2 percent from the 1999–2000 period. Finally, of individuals with drug-resistant HIV, none identified before 1999 was resistant to all three classes of drugs compared to 75 percent of the individuals from the 1999–2000 period.

Drug Resistance in San Francisco

Individuals identified with resistant strains underwent a longer period of time to achieve viral suppression.
Genotypic analysis of blood from individuals newly infected with HIV in the San Francisco Bay Area revealed the emergence of cases resistant to non-nucleoside reverse transcriptase inhibitors. Multidrug resistance was rare but could increase over time.

Researchers excluded participants who had received HIV antiviral therapy for more than seven days. The demographic characteristics of the 225 participants were comparable to those of new San Francisco cases in 1997: 91 percent were men and the average age of the participants was 35 years. Researchers performed phenotypic analysis to determine the concentration of drug required to reduce the viral load by 50 percent and genotypic analysis of HIV genes known to confer drug resistance. The results of this resistance analysis were determined before treatment in 96 percent of participants and during the first week of treatment for the remaining 4 percent.

The number of participants resistant to non-nucleoside reverse transcriptase inhibitors increased from zero for those infected during the 1996-1997 period to 13.2 percent for those infected during 2000-2001. The number of participants resistant to protease inhibitors increased from 2.5 percent to 7.7 percent during this same period. For nucleoside reverse transcriptase inhibitors, however, the presence of resistant mutations fluctuated over the study period, beginning at 25.0 percent for people infected during 1996–1997, dropping to 7.4 percent for the period 1998–1999, and increasing to 20.9 for the period 2000–2001.

HIV Counseling by Physicians

Haidet P, Stone DA, Taylor WC, et al. When risk is low: Primary care physicians’ counseling about HIV prevention. Patient Education and Counseling, 2002; 46(1): 21–29. (Houston Veterans Medical Center; and Beth Israel Deaconess Medical Center, Boston.)

A survey of primary care physicians who reported counseling about HIV revealed that 75 percent of the physicians neglected to explain to their patients the basic principles of HIV testing, such as the potential for false positives, the six month window period after infection in which the virus may not be detectable, and the need for retesting and HIV protection strategies in the interim.

Researchers randomly chose primary physicians from Folio's Medical Directory and undertook telephone interviews with 59 physicians who had reported counseling about HIV in the previous five years. Each physician viewed a series of five vignettes representing patients with a relatively low risk for HIV infection (vignettes ranged from receptive oral sex to monogamous heterosexual and homosexual individuals engaging in either unprotected anal or vaginal intercourse). Researchers audiotaped and analyzed physician responses to the situations and identified general themes.

One common theme was the use of “all or nothing” statements in which the physicians prescribed either maximum preventative measures for any perceived risk or no risk reduction strategies at all. Sixty-nine percent of physicians used these “all or nothing” statements in response to a majority of the vignettes, and of the prescriptive statements respondents made, 92 percent conformed to this “all or nothing” model.

Forty percent of the physicians suggested HIV testing to their patients, and 66 percent attempted to gather more information, including their patients’ HIV risk factors, understanding of HIV disease, previous HIV test results, and perceived HIV risk. Although the study was not designed to compare responses across vignettes, participants did make more “high-risk” determinations in response to the two male homosexual vignettes versus the one heterosexual male vignette and the two heterosexual female vignettes.

Next Month

Next month, FOCUS publishes its Tenth Annual Book Review Issue, including discussions of several books published recently that explore HIV prevention and care.

Among these books are: Aging with HIV: Psychological, Social, and Health Issues, reviewed by James W. Dilley, MD; Beyond Condoms: Alternative Approaches to HIV Prevention, reviewed by Michael Discepolo, MA; Infecting the Treatment: Being an HIV-Positive Analyst, reviewed by Susan Thompson, LMFT; Melancholy and Moralism: Essays on AIDS and Queer Politics, reviewed by Thomas Coates, PhD; Women Who Care: Gender, Race and the Culture of AIDS, reviewed by Diane K. Haas; and “You’re the First One I’ve Told”: New Faces of HIV in the South, reviewed by Kevin Farrell, MSW.
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