HIV TREATMENTS

The most common treatments for HIV infection are antiretrovirals, which inhibit the replication of the virus. Zidovudine, more commonly known as AZT or its brand name, Retrovir, is the most frequently used antiretroviral for HIV. Didanosine (dDI, brand name Videx) and dideoxycytidine (ddC, HIVID) are also antiretrovirals. Other treatments for HIV are being studied either in clinical trials or laboratory research. In addition to treatments for HIV, a variety of drugs are used to prevent certain opportunistic infections that may develop in infected people. The most important preventive, or prophylactic, treatment at early stages of disease is for Pneumocystis carinii pneumonia (PCP), a life-threatening infection that is often the first serious illness to occur in HIV-infected adults.

RESEARCH UPDATE

Approaches to medical treatment of HIV infection have evolved over the past 10 years, and changes continue. Most treatment approaches consist of using one or more antiretroviral drugs along with preventive therapies for opportunistic infections. At an earlier time in the HIV epidemic, people began treatment only when they developed illnesses or when their immune systems were severely suppressed. Today, however, treatments are also recommended at earlier stages of HIV disease when signs of disease progression are detected by laboratory blood tests.

The laboratory test used most often measures T-cell levels. T-cells are white blood cells that help the immune system fight infection. As HIV progresses, the virus attacks and destroys these cells. Treatment intervention is recommended for HIV-infected individuals whose T-cell counts have fallen below 500; healthy, uninfected individuals generally have T-cell levels between 480 and 1,800. T-cell counts are not the sole basis for treatment intervention. Physicians recommend treatment when a person displays symptoms of HIV disease regardless of T-cell levels.

Low T-Cell Counts

Many individuals receiving a positive antibody test result have fewer than 500 T-cells at the time they learn their antibody status. In a study of T-cell levels in patients receiving antibody test results at sexually transmitted disease (STD) clinics in Baltimore, Md., 50% of patients had T-cell levels below 500, and 12% had levels below 200. Most of the patients in the study, including those with T-cell counts below 200, had no symptoms of disease.2

Clinicians recommend early treatment because current therapies appear to be most effective at stages when the immune system is only minimally suppressed. In addition, early treatment slows viral replication and prevents the onset of symptoms or serious opportunistic infections that, once they occur, can cause permanent harm.

The following are the primary treatments for HIV infection that are either available or being studied in clinical trials.

Zidovudine (AZT)

AZT was approved by the Food and Drug Administration (FDA) for people with AIDS in 1987 after a large-scale study found 19 deaths in a group receiving a placebo, but only one death in a group receiving AZT.3 In 1990, the FDA expanded AZT’s approved use to include HIV-infected individuals whose T-cell counts have fallen below 500; healthy, uninfected individuals generally have T-cell levels between 480 and 1,800.1 T-cell counts are not the sole basis for treatment intervention. Physicians recommend treatment when a person displays symptoms of HIV disease regardless of T-cell levels.

In 1990, the FDA expanded AZT’s approved use to include HIV-infected people with T-cell counts of less than 500, regardless of whether they had symptoms of disease. A study that year found that AZT was effective in slowing disease progression and improving the immune status of asymptomatic seropositive individuals with T-cell counts below 500, without producing serious side effects. In this study, 33 of 428 subjects (7.7%) in a placebo group developed AIDS, compared to 11 of 453 subjects (2.4%) receiving AZT. Clinical benefit was most easily demonstrated in subjects who entered the study with T-cell counts between 200 and 499.4

AZT is the most com-
mon treatment for HIV, and, even as other drugs receive approval, it is expected to remain for some time as the treatment of choice for many patients. AZT does not eradicate HIV from the body or from a cell once it is infected, but it suppresses HIV replication and prevents a larger number of cells from becoming infected. Studies suggest the drug has comparable effects in men and women, and no difference in effectiveness among ethnic groups.

The dose for asymptomatic adults is 500 milligrams daily, and for adults with symptoms it is 600 milligrams. Children receive AZT in doses based on their weight. Doses below 500 milligrams have been studied for adults, but are believed to be less effective.

Numerous side effects have been associated with AZT therapy, but the most severe side effects, such as anemia and bone marrow toxicity, have been reported more often among people receiving higher doses than those now recommended. Adverse effects associated with therapy at current dosages include headache, nausea and neutropenia (a shortage of white blood cells essential in fighting bacterial infections). These side effects can subside or increase as therapy continues. People with higher levels of T-cells generally experience fewer side effects than those with severely impaired immune systems.

After six to 12 months of AZT use, HIV may develop strains of virus in the body that are no longer suppressed by the drug. As the strain replicates and becomes dominant, AZT may become ineffective and immune response may decline. Resistance emerges more slowly in patients treated early in HIV disease than in patients treated at later stages. However, the emergence of resistance alone does not mean AZT therapy should automatically stop, because the drug may continue to have some effectiveness.

ddI (didanosine)

The FDA has approved the use of ddI for adults and children who cannot tolerate or do not benefit from AZT. In practice, however, access extends beyond these guidelines, as private physicians take a role in determining who will receive the drug. ddI works in much the same way as AZT, but because it has different side effects, it works better for some patients. Preliminary results from one study indicated that about half the patients who took ddI showed improvements in T-cell levels. The FDA-approved adult dose for ddI is based on body weight; the drug's optimal dose has not yet been determined. Current studies at 200 to 500 milligrams daily appear to produce clinical benefit without causing the severe toxicity experienced at higher doses.

The use of ddI is potentially limited by several serious side effects. The drug's manufacturer has stated that ddI can cause pancreatitis, a serious inflammation of the pancreas, in 5 to 9% of patients, and peripheral neuropathy, which is characterized by numbness, tingling or pain in the feet or hands, in 16 to 24% of patients.

ddC (dideoxycytidine)

The FDA has not approved ddC, but the drug is available through an expanded access program, similar to one that initially made ddI available. To be eligible for the program, patients must be intolerant to AZT, or have failed to benefit from AZT.

Studies comparing AZT with ddC have shown that more opportunistic infections have occurred among subjects taking ddC. Like ddI, ddC can produce side effects, including peripheral neuropathy and pancreatitis.

Combination Therapy

Taking two or more antiretroviral drugs at the same time or alternately may produce greater benefit than taking only a single drug. Many researchers and clinicians believe that combination therapies may be the most effective way to manage HIV disease.

Preliminary studies have found an increased benefit in patients combining ddC with AZT compared to those taking AZT alone. Studies show that combination therapy may also be effective in reducing some of the side effects of a drug and in reducing resistance that can develop when only a single drug is taken. For instance, while AZT may cause anemia and ddI may cause peripheral neuropathy, alternating periods of AZT with periods of ddI may stop both of these side effects from develop-
ing or becoming serious while still maintaining antiviral activity.\textsuperscript{9}

In addition, a treatment combination may be useful in fighting resistance. A small study found that alternating ddI with AZT reduced resistance that developed when patients took AZT alone.\textsuperscript{10}

Combination therapy is viewed with a great deal of promise because historically it has improved patient outcome in other life-threatening illnesses. In addition, it is looked to with hope because single antiretroviral agents have not been able to permanently stop disease progression among people at advanced stages of illnesses.

**PCP Prevention**

PCP, a form of pneumonia that often occurs in the lungs, is the leading cause of death among people with AIDS. Preventive therapies can greatly reduce the risk of initial onset of PCP. PCP prophylaxis is recommended when T-cell counts fall to between 250 to 200; PCP rarely occurs above this level.

At one time, pentamidine, given in aerosolized form, was considered the most effective method of PCP prevention. However, sulfa-based drugs such as Dapsone or trimethoprim-sulfamethoxazole (TMP-SMX, brand names Septra and Bactrim) now appear to be more effective at preventing PCP, and are commonly prescribed instead of aerosolized pentamidine.\textsuperscript{11}

Aerosolized pentamidine is effective against PCP in the lungs, but not elsewhere. TMP-SMX and Dapsone are more effective at protecting the entire body from PCP, and TMP-SMX may be helpful in preventing toxoplasmosis and cytomegalovirus (CMV) infections. TMP-SMX and Dapsone are taken orally and therefore are easier to take, and much less expensive.

**Other Infections**

Some people take preventive therapies, or prophylaxis, for other life-threatening infections, such as fungal infections, toxoplasmosis and CMV infections. While the FDA has not approved any treatments to prevent the first episode of these opportunistic infections, some physicians believe preventive treatments may be beneficial. They prescribe experimental therapies to prevent these infections when a patient’s T-cell count falls below 150 or when a person has one of these infections.\textsuperscript{12}

Drugs recommended as preventive therapies are often the same treatments used to treat the disease when it is acute, and in some cases they have proven effective at preventing recurrent episodes of disease. However, as preventive therapies, these drugs are still being studied and are consid-

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**A Related Issue: Paying For Treatments**

Concern about the cost of treatments keeps many people from pursuing treatment intervention after receiving a positive test result. There are options that make treatments more accessible for people with limited resources.

Most private insurance companies and health maintenance organizations pay at least part of the cost of drugs that have been approved by the Food and Drug Administration (FDA) when those drugs are used for their approved purposes. There are exceptions; some insurance companies pay for only some drugs, while others establish separate criteria based on the health of the insured person.

In California, the Department of Health Services, Office of AIDS, administers the AIDS Drug Program (ADP), which pays for AZT, ddI, aerosolized pentamidine, Dapsone and trimethoprim-sulfamethoxazole (TMP-SMX). The program also covers sulfadiazine (for PCP), pyrimethamine (toxoplasmosis), clindamycin (toxoplasmosis), ganciclovir (CMV retinitis), and nystatin (candidiasis).

In addition, beginning in April 1992, the program will cover clotrimazole, fluconazole and ketoconazole (for fungal infections). To be eligible for full coverage of these drugs, a person must have an adjusted gross income of less than $26,480 annually. People earning between this amount and $50,000 are eligible for partial reimbursement. For more information, contact a local public health department.

California’s Early Intervention Program offers free medical exams, including prescriptions, to people with HIV. Sites are located in San Diego, Santa Ana, Long Beach, Los Angeles, Riverside, Palm Springs, San Bernardino, Fremont, San Mateo, San Francisco, Berkeley, Sacramento and San Leandro. For more information about the location of centers, clients or counselors can call their local health department or the Office of AIDS.

Other insurance plans, such as Medi-Cal and Medicaid, pay the cost of medical care and some treatments for those who qualify. Some of these plans require that a person have an AIDS diagnosis to qualify. Public health departments can provide more information about these plans.
tive use. People with HIV are encouraged to be screened annually for TB infection by a skin test (PDD) and chest x-ray.  

For gynecological conditions, including human papilloma virus, regular clinical exams and Pap smears are important, though no preventative treatment is available.  

Experimental Treatments  
A number of unproven treatments for HIV disease are being studied in laboratory and clinical research. Experimental treatments must withstand several years of study to complete the trials necessary for approval; some will never be approved. Historically, some experimental treatments have proven too toxic for use; and others, which have showed promise in initial laboratory studies, have proved to have little or no effectiveness in humans.  

Individuals receive some experimental treatments, such as immune modulators and unapproved antiretroviral drugs, through clinical trials or through buyers' clubs or other underground sources. Buyers' clubs are groups or individuals that purchase unapproved drugs and make them available to people with HIV.  

Immune modulators are drugs capable of modifying or regulating the immune system, as opposed to fighting the virus, which is what antiretrovirals do. Immune modulators include alpha interferon, tumor necrosis factor, interleukin-2, naltrexone and disulfiram. Some researchers have suggested that ideal treatment of HIV would involve a combination of antiretroviral and immune modulators.  

Antiretrovirals other than AZT, ddI and ddC include protease inhibitors, TIBO derivatives, hypercin, tat gene inhibitors, and reverse transcriptase inhibitors. These drugs act at a different point in the life cycle of HIV from the approved antiretrovirals, and therefore it is hoped that they may be less likely to be carcinogenic, to trigger resistant strains of HIV, and to have major side effects.  

In laboratory studies, some of these drugs have shown effectiveness at preventing infected cells from releasing virus, and at preventing free-floating HIV from infecting healthy cells. 

References  
A Related Issue: Understanding Clinical Trials

After drugs have shown promise in laboratory studies, but before they can be approved for widespread use, they are studied in clinical trials to determine their safety and effectiveness for humans.

Clinical trials provide people access to treatments that may be unavailable elsewhere.

For participants, clinical trials have other benefits as well as some drawbacks. Some of the advantages are:

- Participants receive treatments free of charge.
- Participants receive monitoring of their health by methods that are often unavailable or prohibitively expensive elsewhere.
- A trial serves as a personal empowerment tool and is a way of taking action to benefit one’s health and contribute to medical research.

Some of the disadvantages are:
- A trial is a risky endeavor because it is an experiment. Drugs may cause damaging side effects and may have no benefit.
- There are strict criteria a person must meet before being allowed in a clinical trial.
- Participants may be responsible for some of the medical costs of the trial.
- People may hastily enter a trial soon after learning of their infection, but later feel they had not prepared themselves for such a dramatic step.


IMPLICATIONS FOR COUNSELING

Treatment information has become an essential part of the counseling session for clients who are HIV antibody positive. At the time they receive their test results, a significant number of people are at a stage of HIV disease in which they can greatly benefit from immediate treatment intervention.

Introduce a discussion of treatments during pre-test counseling. It is at this time that clients are more receptive to counseling and to receiving new information. In addition, a discussion of treatments and intervention options in the pre-test session can help prepare a client for responding to a positive result. Clients often do not accept information, especially new information, once they receive a positive result.

All clients who are antibody positive need to know that treatments are available and are important in maintaining health. They also need to understand the types of available drugs and treatment options. Some clients have a thorough knowledge of treatments, but others may know little or may believe treatments are only for symptomatic people.

Counselors can initiate discussions about treatments by providing the client with information about the following basic ideas:

• Early intervention is important. Many people are not aware that the progression of HIV infection and the health of the immune system can be determined long before opportunistic conditions occur. Researchers recommend that treatment with AZT begin when a person has symptoms of disease or when a person’s T-cell count falls below 500, regardless of whether that person has developed symptoms of disease. Many people who receive their positive antibody test results have reached this point.

• Treatments are available and effective. AZT and other treatments are widely accepted by physicians.
as important in preventing disease progression. Many people fail to understand the breadth of available treatments. Clients may be intimidated by the complexity of treatment-related information or they may have beliefs that are based on information from several years ago when treatment options were limited. There has been considerable controversy surrounding the effectiveness and side effects of treatments, and clients' beliefs may discourage them from seeking care.

- Financial assistance is available. In California, people may qualify for partial or full payment for treatments through several programs (please see "A Related Issue: Paying for Treatments"). Inexpensive or free medical care from public clinics may also be available. Provide referrals to local health departments and social service organizations for more information about financial assistance.

Hesitation to Accept Treatment Information

Clients may hesitate to accept or act on information about treatments for many reasons. The following are some of the reasons:

- Clients refuse to accept that they are antibody positive. For clients to act on treatment information, they must, in most cases, accept their antibody status. They may not accept that their immune system is deteriorating and will benefit from early treatment.
- Clients believe treatment information is important only for people who are symptomatic.
- Clients feel that treatment intervention is a step into the health care system from which they will never return. Many hesitate to receive treatments because they believe that once they begin, they will never again be free of treatments. If they remain free of treatments, they may see their lives as less hindered by HIV.
- Clients do not expect antibody positive results, and therefore are overwhelmed by the result and the range of information delivered with it.
- Clients fear discrimination from insurers, employers or friends.
- Clients have depression that keeps them from seeking intervention.
- Clients believe that because there is no cure for HIV infection, there is no reason to receive treatments. This belief, perhaps more common when fewer treatments were available, can be addressed by stressing that while there is no cure, treatments are more effective at slowing the progression of disease and allowing people to maintain their health until more effective treatments are developed.

Talk with clients about their hesitation, and provide information that might help them question or reduce this. Acknowledge that concerns about treatments are valid and that intervention is a significant and dramatic step in someone's life. Remind clients that they have already taken an important first step in maintaining their health, and that they are now ready to take the logical and beneficial next step: treatment.

Hope vs. False Hope

Counseling about treatments provides the counselor a chance to offer a client hope, which is especially important at a time when clients are susceptible to fear or depression, or may become resigned to illness or death.

Counselors must balance the hope that is necessary to motivate clients to face their illness with the false hope that can lead to denial of the seriousness of HIV disease. Available treatments do not cure HIV infection, and clients need to know this. Clients should understand they are living with a life-

A COUNSELOR'S PERSPECTIVE

I have trouble keeping up with treatment information. Once I finally learned about AZT, there were new treatments to find out about. Now I figure it is an important part of my counseling and my self-education, and I stay up-to-date on the basics.

I used to figure I had too much to cover with antibody positive clients to worry about treatment information. Now I always integrate the information because treatment options are so related to the emotional reactions of clients. I can respond to their feelings of desperation, and the sense that there is nothing for them.
Case Study

Michael, who has just been given a positive test result, is a 35-year-old injection drug user. He has had little experience with the health care system, was last treated for an STD five years ago, and is resistant to seeking care now. When asked about treatments, he responds that he doesn’t believe they will be of much use because they offer no hope of curing him.

Counseling Intervention

Ask more about Michael’s thoughts of treatments and medical care to learn what information he has and what beliefs he holds that lead him to resist medical intervention. Michael may have formed rigid opinions about treatment based on information he gathered several years ago.

Make sure Michael has adequate information about the availability, usefulness and affordability of treatments and document the importance of treatments for staying healthy. Acknowledge the truth of his belief that there is currently no cure for HIV, while making him aware that treatments are keeping people alive and healthier longer, and that research continues to seek new agents that could be more effective or lead to a cure for the disease.

This information may not change Michael’s beliefs during the counseling session, but it can provide him motivation to reconsider his thoughts at a later time.

Be a “cheerleader” for the part of Michael that has elected to seek an antibody test. Interpret his motivation as an affirmative action for himself, and emphasize that follow-up care and early intervention will be a continuation of that action.

Find out what has motivated Michael to get tested, what he expected his test result to be or how he imagined he would react to getting a negative or positive result. Perhaps Michael will acknowledge that he did not want to receive a positive result and therefore treatment information is unexpected.

Help Michael see that the steps to take to seek treatment intervention are related to the steps he took to take an antibody test and receive the result.

Discuss Michael’s fatalistic thoughts, and the reasons for his depression or low self-esteem. Let him know that treatments can be effective not only for extending his life, but also for helping to avoid infections and illnesses that could seriously impair his health.

Provide a list of referrals for health care, particularly a public health clinic if he has few financial resources. Also, provide referrals for social support to help Michael face his resistance to treatment and gain access to care and other needed services.

Help Michael understand that by continuing to use injection drugs, he is significantly endangering his health. In using injection drugs, he may expose his immune system to serious infections that his body cannot adequately fight because his immune system is already impaired by HIV. Let Michael know that he can take steps to improve the quality of his life by seeking support to stop his drug use. Provide him with information about the need to protect his health and the health of others by refraining from unsafe needle using behaviors and unsafe sex.

threatening infection that can be managed with ongoing medical care and self-care, and that lack of treatment is known to significantly reduce chances for survival.

Offering Further Help

Make clients aware of their treatment options. Provide a list of referrals for follow-up care to allow a person to choose a health care practitioner he or she will be comfortable with. At some locations where post-test counseling is given, counselors are able to provide clients with referrals to health care centers in the same building.

Provide a referral list with names, telephone numbers and other basic information, and provide support to give the client confidence to take charge of his or her health care to make a necessary appointment. And, offer information about the availability of services in the state’s Early Intervention Program and at the growing number of local and community-based early intervention facilities.

Fitting It In

In many cases, counselors may not have time to devote to a discussion of treatments. For instance, the test session may be largely devoted to responding to a client’s shock or disbelief in response to a test result. In such cases, counselors may only be able to mention the importance of treatments and provide information clients can take away from the test counseling session.

Often, treatments may be best covered when integrated into broader discussions, for instance, during talks about early intervention, survival or taking care of oneself.
TEST YOURSELF

1. True or False: AZT is the only available treatment for HIV infection.
2. Which of the following may be recommended by physicians as prophylaxis for Pneumocystis carinii pneumonia (PCP)? a) pentamidine, b) Septra, c) Dapsone, d) any of the above may be recommended.
3. True or False: Nearly all antibody test clients should begin AZT treatment immediately after receiving a positive test result.
4. True or False: Financial assistance is not available to provide treatments for people with limited financial resources and limited income.
5. True or False: AZT produced more adverse side effects when taken at dosages higher than those currently recommended.
6. True or False: Combination drug therapies may be more effective than therapy with a single agent.
7. Studies have found that AZT is effective at a) slowing the progression of HIV, b) eliminating HIV from the body, c) creating new T-cells, d) none of the above.
8. True or False: While AZT, ddI and ddC are in the same family of drugs, some people may show better results or fewer side effects with one drug compared to another.

DISCUSSION QUESTIONS

- In what ways can counselors help ensure that clients will see a medical provider after receiving a positive test result? What motivational techniques might counselors use for doing this?
- When might a discussion of treatments be relevant for someone who is antibody negative? What information might be included in such a discussion?
- Clients may react to a positive test result with an extended period of shock, and therefore may be unreceptive to a thorough discussion of HIV treatments. What counseling can be offered for this client?
- Maintaining current treatment information is difficult. How can counselors stay up-to-date with treatment information? Why is it important for antibody test counselors to be aware of recent treatment research?
- Some clients believe strongly that the discovery of a cure for HIV is imminent. Can this belief be harmful? How can the counselor offer a client hope without leading the client to hold false hopes?

Answers to Test Yourself

1. False. AZT and ddI are both approved to treat HIV, and other drugs are available in clinical trials and through buyers' clubs.
2. D. Any of these drugs may be recommended as prophylaxis for PCP.
3. False. While studies show that a significant number of people are at a stage of infection in which treatment intervention is recommended at the time they receive their antibody test result, many others have not reached this stage. All antibody positive clients should visit a physician after their test result.
4. False. Public assistance is available from several sources, including California's AIDS Drug Program (ADP).
5. True. At current commonly prescribed dosage levels, AZT produces fewer side effects compared to those experienced at higher levels previously prescribed.
6. True. Combination therapies may produce more effectiveness against HIV than a single agent.
7. A. Studies have found that AZT is effective at slowing progression of HIV.
8. True. People may respond better to one drug compared to another.