IA AMERICAN™
LIFE INSURANCE COMPANY
P.O. Box 2549 • Waco, TX 76702-2549
254-297-2774

HIV TESTING NOTICE AND INFORMED CONSENT FORM

PURPOSE OF CONSENT FORM

To evaluate your insurability, the Insurer named above (the "Insurer") has requested that you provide a sample of blood, urine, or oral fluid for HIV testing (the "HIV test" or "test"). The HIV test may include, but is not necessarily limited to, testing for the presence of Human Immunodeficiency Virus (HIV) antibodies/antigens. The testing will be performed by a licensed laboratory. By signing this form, you agree that the test may be done, that the test results may be disclosed as described in this form, and that underwriting and/or coverage decisions will be based on the test results. As a result, it is important that you carefully read this HIV Testing Notice and Informed Consent Form prior to consenting to such a test and disclosure.

INFORMATION ON AIDS

Acquired Immunodeficiency Syndrome (AIDS) is a life-threatening disorder of the immune system, caused by a virus, HIV. The virus is transmitted by sexual contact with an infected person, from an infected mother to her newborn infant, or by exposure to infected blood (as in needle sharing during injection drug use). AIDS does not typically develop until a person has been infected with HIV for several years. A person may remain free of symptoms for years after becoming infected. Infected persons have a significant chance of developing AIDS over the next 10 years.

THE HIV TEST

Before consenting to testing, please read the following important information:

1. **Purpose.** The purpose of this HIV test is to determine insurability. This test is being performed to determine whether you may have been infected with HIV. If you are infected you are probably not insurable. This test is not a test for AIDS; AIDS can only be diagnosed by medical evaluation. An HIV antibody/antigen test detects antibodies and/or antigens to the HIV virus, the causative agent for AIDS, and shows whether you may have been exposed to the virus.
2. **Positive Test Results.** If you test positive, it does not mean that you have AIDS, but that you may be at significantly increased risk of developing AIDS or AIDS-related conditions. If you test positive, you should seek full medical evaluation with your personal physician or a physician at a public health clinic.
3. **Indeterminate Test Results.** If your test result is indeterminate you should obtain further medical evaluation to determine the significance of this finding in your situation.
4. **Accuracy.** An HIV antibody/antigen test is reliable but not 100% accurate. It is possible, but rare, that an HIV antibody/antigen test may provide a positive result even if you are not infected. In this case retesting should be done to confirm the validity of a positive test. It is also possible that an HIV antibody/antigen test may provide a negative result even though you are infected. This happens most commonly in recently infected persons; it takes at least 4-12 weeks for a positive test result to develop after a person is infected.
5. **Side Effects.** A positive test result may cause you significant anxiety. A positive test may result in a finding of uninsurability in connection with this insurance application, as well as for life, health, or disability insurance policies you may apply for in the future. A negative result may create a false sense of security.
6. **Confidentiality.** All test results will be treated confidentially. However, in signing this HIV Testing Notice and Informed Consent Form, you authorize the testing laboratory to report the test results to the Insurer. The Insurer will treat the test results as confidential, but your test results may be provided to affiliates, reinsurers, employees and contractors of the Insurer who are involved in handling or determining your application for coverage or claims. Your test results will not be disclosed to your agent or broker. A positive or indeterminate test result may be reported to the Medical Information Bureau, Inc. (MIB), which is a national insurance data bank. The report will use a generic code to report a nonspecific blood disorder. Please also be advised that the jurisdiction in which you reside may require reporting of positive HIV test results or other test results by the Insurer and/or the laboratory that conducts the test to a regulatory agency.

7. **Notification of Test Results.** If your HIV test results are negative, no routine notification will be sent to you. If the HIV test results are positive or indeterminate, the Insurer will send the test results to the physician designated in this HIV Testing Notice and Informed Consent Form, and you will be advised to contact the physician regarding the test results. If you have not designated a physician in this form, the Insurer will contact you and ask that you name a physician to whom the HIV test results may be sent.

   If you fail to designate a physician, the Insurer will provide the Delaware Department of Health and Social Services with information necessary to locate you and inform you of your HIV test results.

8. **Further Information.** Further information about HIV testing and AIDS can be obtained by contacting your personal physician, the State Department of Health, as well as any AIDS information organization in your area.

CONSENT

I hereby acknowledge that I have received, read and understand the HIV Testing Notice and Informed Consent Form.

I understand that the results of the HIV test will be used in determining insurability.

I authorize the testing laboratory to disclose the results of the HIV test to the Insurer.

I authorize the Insurer to disclose the HIV test result to its reinsurers, affiliates, employees and contractors involved in making an underwriting or coverage determination regarding my application or claim and to whom such disclosure is necessary.

I understand that the Insurer will disclose a positive or indeterminate HIV test result to a physician designated by me. I understand that any such disclosure will be in a manner that assures confidentiality. I authorize the Insurer to disclose a positive or indeterminate test result to the following physician:

Physician: _____

Address: _____

City, State, Zip: _____

If I fail to designate a physician in the space above, I understand that in the event of a positive or indeterminate HIV test result, the Insurer will contact me and ask that I then name a physician to whom the HIV test result may be disclosed.

I understand that if I fail to designate a physician, the Insurer will provide the Delaware Department of Health and Social Services with information necessary to locate me and inform me of the test results.

I authorize the Insurer to report a positive or indeterminate HIV test result to the Medical Information Bureau, Inc. I understand that any such report will use a generic code to report a non-specific blood disorder.

I acknowledge that prior to testing I received a copy of the brochure titled “HIV Infection and AIDS: An Overview” published by the National Institute of Allergy and Infectious Diseases of the National Institutes of Health of the U.S. Department of Health and Human Services.

I voluntarily consent to the collection of a sample of blood, urine or oral fluid from me, the testing of the sample(s), and the disclosure of the test results as described above.

A photocopy will be as valid as the original.

_____ _____

Signature of Proposed Insured or Person Authorized by Law to Consent on behalf of the Proposed Insured. Date

October 2007

HIV Infection and AIDS: An Overview

OVERVIEW

AIDS was first reported in the United States in 1981 and has since become a major worldwide epidemic. AIDS is caused by the human immunodeficiency virus, or HIV. By killing or damaging cells of the body's immune system, HIV progressively destroys the body's ability to fight infections and certain cancers. People diagnosed with AIDS may get life-threatening diseases called opportunistic infections. These infections are caused by microbes such as viruses or bacteria that usually do not make healthy people sick.

Since 1981, more than 980,000 cases of AIDS have been reported in the United States to the Centers for Disease Control and Prevention (CDC). According to CDC, more than 1,000,000 Americans may be infected with HIV, one-quarter of whom are unaware of their infection. The epidemic is growing most rapidly among minority populations and is a leading killer of African-American males ages 25 to 44. According, AIDS affects nearly seven times more African Americans and three times more Hispanics than whites. In recent years, an increasing number of African-American women and children are being affected by HIV/AIDS.

TRANSMISSION

HIV is spread most often through unprotected sex with an infected partner. The virus can enter the body through the lining of the vagina, vulva, penis, rectum, or mouth during sex.

Risky behavior

HIV can infect anyone who practices risky behaviors such as:

- Sharing drug needles or syringes
- Having sexual contact, including oral sexual contact, with an infected person without using a condom
- Having sexual contact with someone whose HIV status is unknown

Infected blood

HIV also is spread through contact with infected blood. Before donated blood was screened for evidence of HIV infection and before heat-treating techniques to destroy HIV in blood products were introduced, HIV was transmitted through transfusions of contaminated blood or blood components. Today, because of blood screening and heat treatment, the risk of getting HIV from blood transfusions is extremely small.

Contaminated needles

HIV is often spread among injection drug users when they share needles or syringes contaminated with very small quantities of blood from someone infected with the virus.

It is rare for a patient to be the source of HIV transmitted to a healthcare provider or vice versa by accidental sticks with contaminated needles or other medical instruments.

Mother to child

Women can transmit HIV to their babies during pregnancy or birth. Approximately one-quarter to one-third of all untreated pregnant women infected with HIV will pass the infection to their babies. HIV also can be spread to babies through the breast milk of mothers infected with the virus. If the mother takes certain drugs during pregnancy, she can significantly reduce the chances that her baby will get infected with HIV. If healthcare providers treat HIV-infected pregnant women and deliver their babies by cesarean section, the chances of the baby being infected can be reduced to a rate of 1 percent. HIV infection of newborns has been almost eradicated in the United States because of appropriate treatment.

A study sponsored by the National Institute of Allergy and Infectious Diseases (NIAID) in Uganda found a highly effective and safe drug for preventing transmission of HIV from an infected mother to her newborn. Independent studies have also confirmed this finding. This regimen is more affordable and practical than any other examined to date. Results from the study show that a single oral dose of the antiretroviral drug nevirapine (NVP) given to an HIV-infected woman in labor and another to her baby within 3 days of birth reduces the transmission rate of HIV by half compared with a similar short course of AZT (azidothymidine).

Saliva

Although researchers have found HIV in the saliva of infected people, there is no evidence that the virus is spread by contact with saliva. Laboratory studies reveal that saliva has natural properties that limit the power of HIV to infect, and the amount of virus in saliva appears to be very low. Research studies of people infected with HIV have found no evidence that the virus is spread to others through saliva by kissing. The lining of the mouth, however, can be infected by HIV, and instances of HIV transmission through oral intercourse have been reported.

Scientists have found no evidence that HIV is spread through sweat, tears, urine, or feces.

Casual contact

Studies of families of HIV-infected people have shown clearly that HIV is not spread through casual contact such as the sharing of food utensils, towels and bedding, swimming pools, telephones, or toilet seats. HIV is not spread by biting insects such as mosquitoes or bedbugs.

Sexually transmitted infections

People with a sexually transmitted infection, such as syphilis, genital herpes, chlamydia, gonorrhea, or bacterial vaginosis, may be more susceptible to getting HIV infection during sex with infected partners.

SYMPTOMS

Early symptoms

Many people will not have any symptoms when they first become infected with HIV. They may, however, have a flu-like illness within a month or two after exposure to the virus. This illness may include:

- Fever
- Headache
- Tiredness
- Enlarged lymph nodes (glands of the immune system easily felt in the neck and groin)

These symptoms usually disappear within a week to a month and are often mistaken for those of another viral infection. During this period, people are very infectious, and HIV is present in large quantities in genital fluids.

Later symptoms

More persistent or severe symptoms may not appear for 10 years or more after HIV first enters the body in adults, or within 2 years in children born with HIV infection. This period of asymptomatic infection varies greatly in each person. Some people may begin to have symptoms within a few months, while others may be symptom-free for more than 10 years.

Even during the asymptomatic period, the virus is actively multiplying, infecting, and killing cells of the immune system. The virus can also hide within infected cells and be inactive. The most obvious effect of HIV infection is a decline in the number of CD4 positive T (CD4+) cells found in the blood-the immune system's key infection fighters. The virus slowly disables or destroys these cells without causing symptoms.

As the immune system becomes more debilitated, a variety of complications start to take over. For many people, the first signs of infection are large lymph nodes, or swollen glands that may be enlarged for more than 3 months. Other symptoms often experienced months to years before the onset of AIDS include:

- Lack of energy
- Weight loss
- Frequent fevers and sweats
- Persistent or frequent yeast infections (oral or vaginal)
- Persistent skin rashes or flaky skin
- Pelvic inflammatory disease in women that does not respond to treatment
- Short-term memory loss

Some people develop frequent and severe herpes infections that cause mouth, genital, or anal sores, or a painful nerve disease called shingles. Children may grow slowly or get sick a frequently.

WHAT IS AIDS?

Symptoms of opportunistic infections common in people with AIDS include:

- Coughing and shortness of breath
- Seizures and lack of coordination
- Difficult or painful swallowing

WHAT IS AIDS? (cont'd)

- Mental symptoms such as confusion and forgetfulness
- Severe and persistent diarrhea
- Fever
- Vision loss
- Nausea, abdominal cramps, and vomiting
- Weight loss and extreme fatigue
- Severe headaches
- Coma

Children with AIDS may get the same opportunistic infections as do adults with the disease. In addition, they also may have severe forms of the typically common childhood bacterial infections, such as conjunctivitis (pink eye), ear infections, and tonsillitis.

People with AIDS are also particularly prone to developing various cancers, especially those caused by viruses such as Kaposi's sarcoma and cervical cancer, or cancers of the immune system known as lymphomas. These cancers are usually more aggressive and difficult to treat in people with AIDS. Signs of Kaposi's sarcoma in light-skinned people are round brown, reddish, or purple spots that develop in the skin or in the mouth. In dark-skinned people, the spots are more pigmented.

During the course of HIV infection, most people experience a gradual decline in the number of CD4+ T cells, although some may have abrupt and dramatic drops in their CD4+ T-cell counts. A person with CD4+ T cells above 200 may experience some of the early symptoms of HIV disease. Others may have no symptoms even though their CD4+ T-cell count is below 200.

Many people are so debilitated by the symptoms of AIDS that they cannot hold a steady job or do household chores. Other people with AIDS may experience phases of intense life-threatening illness followed by phases in which they function normally.

A small number of people first infected with HIV 10 or more years ago have not developed symptoms of AIDS. Scientists are trying to determine what factors may account for the lack of progression to AIDS in some people, such as:

- Whether their immune systems have particular characteristics
- Whether they were infected with a less aggressive strain of the virus
- If their genes may protect them from the effects of HIV

Scientists hope that understanding the body's natural method of controlling infection may lead to ideas for protective HIV vaccines and use of vaccines to prevent the disease from progressing.

DIAGNOSIS

Because early HIV infection often causes no symptoms, a healthcare provider usually can diagnose it by testing blood for the presence of antibodies (disease-fighting proteins) to HIV. HIV antibodies generally do not reach noticeable levels in the blood for 1 to 3 months after infection. It may take the antibodies as long as 6 months to be produced in quantities large enough to show up in standard blood tests. Hence, to determine whether a person has been recently infected (acute infection), a healthcare provider can screen blood for the presence of HIV genetic material. Direct screening of HIV is extremely critical in order to prevent transmission of HIV from recently infected individuals.

Anyone who has been exposed to the virus should get an HIV test as soon as the immune system is likely to develop antibodies to the virus-within 6 weeks to 12 months after possible exposure to the virus. By getting tested early, a healthcare provider can give advice to an infected person about when to start treatment to help the immune system combat HIV and help prevent the emergence of certain opportunistic infections (see section on treatment). Early testing also alerts an infect person to avoid high-risk behaviors that could spread the virus to others.

Most healthcare providers can do HIV testing and will usually offer counseling at the same time. Of course, testing can be done anonymously at many sites if a person is concerned about confidentiality.

Healthcare providers diagnose HIV infection by using two different types of antibody tests: ELISA (enzyme-linked immunosorbent assay) and Western blot. If a person is highly likely to be infected with HIV but has tested negative for both tests, a healthcare provider may request additional tests. A person also may be told to repeat antibody testing at a later date, when antibodies to HIV are more likely to have developed.

Babies born to mothers infected with HIV may or may not be infected with the virus, but all carry their mothers' antibodies to HIV for several months.

If these babies lack symptoms, healthcare providers cannot make a definitive diagnosis of HIV infection using standard antibody tests. Instead, they are using new technologies to detect HIV and more accurately determine HIV infection in infants between ages 3 months and 15 months. Researchers are evaluating a number of blood tests to determine which ones are best for diagnosing HIV infection in babies younger than 3 months.

TREATMENT

When AIDS first surfaced in the United States, there were no drugs to combat the underlying immune deficiency and few treatments existed for the opportunistic diseases that resulted. Researchers, however, have developed drugs to fight both HIV infection and its associated infections and cancers.

HIV infection

The Food and Drug Administration (FDA) has approved a number of drugs for treating HIV infection. The first group of drugs, called reverse transcriptase (RT) inhibitors, interrupts an early stage of the virus making copies of itself. Nucleoside/nucleotide RT inhibitors are faulty DNA building blocks. When these faulty pieces are incorporated into the HIV DNA (during the process when the HIV RNA is converted to HIV DNA), the DNA chain cannot be completed, thereby blocking HIV from replicating in a cell. Non-nucleoside RT inhibitors bind to reverse transcriptase, interfering with its ability to convert the HIV RNA into HIV DNA. This class of drugs may slow the spread of HIV in the body and delay the start of opportunistic infections.

FDA has approved a second class of drugs for treating HIV infection. These drugs, called protease inhibitors, interrupt the virus from making copies of itself at a later step in its life cycle.

FDA also has introduced a third new class of drugs, known at fusion inhibitors, to treat HIV infection. Fuzeon (enfuvirtide or T-20), the first approved fusion inhibitor, works by interfering with the ability of HIV-1 to enter into cells by blocking the merging of the virus with the cell membranes. This inhibition blocks HIV's ability to enter and infect the human immune cells. Fuzeon is designed for use in combination with other anti-HIV treatments. It reduces the level of HIV infection in the blood and may be effective against HIV that has become resistant to current antiviral treatment schedules.

Because HIV can become resistant to any of these drugs, healthcare providers must use a combination treatment to effectively suppress the virus. When multiple drugs (three or more) are used in combination, it is referred to as highly active antiretroviral therapy, or HAART, and can be used by people who are newly infected with HIV as well as people with AIDS. Recently, FDA approved the first one-a-day three drug-combination pill called Atripla.

Researchers have credited HAART as being a major factor in significantly reducing the number of deaths from AIDS in this country. While HAART is not a cure for AIDS, it has greatly improved the health of many people with AIDS and it reduces the amount of virus circulating in the blood to nearly undetectable levels. Researchers, however, have shown that HIV remains present in hiding places, such as the lymph nodes, brain, testes, and retina of the eye, even in people who have been treated.

Side effects

Despite the beneficial effects of HAART, there are side effects associated with the use of antiviral drugs that can be severe. Some of the nucleoside RT inhibitors may cause a decrease of red or white blood cells, especially when taken in the later stages of the disease. Some may also cause inflammation of the pancreas and painful nerve damage. There have been reports of complications and other severe reactions, including death, to some of the antiretroviral nucleoside analogs when used alone or in combination. Therefore, health experts recommend that anyone on antiretroviral therapy be routinely seen and followed by their healthcare provider.

The most common side effects associated with protease inhibitors include nausea, diarrhea, and other gastrointestinal symptoms. In addition, protease inhibitors can interact with other drugs resulting in serious side effects. Fuzeon may also cause severe allergic reactions such as pneumonia, trouble breathing, chills and fever, skin rash, blood in urine, vomiting, and low blood pressure. Local skin reactions are also possible since it is given as an injection underneath the skin. People taking HIV drugs should contact their healthcare providers immediately if they have any of these symptoms.

Opportunistic infections

A number of available drugs help treat opportunistic infections. These drugs include:

- Foscarnet and ganciclovir to treat CMV (cytomegalovirus) eye infections
- Fluconazole to treat yeast and other fungal infections
- TMP/SMX (trimethoprim/sulfamethoxazole) or pentamidine to treat PCP (Pneumocystis carinii pneumonia)

Cancers

Healthcare providers use radiation, chemotherapy, or injections of alpha interferon-a genetically engineered protein that occurs naturally in the human body-to treat Kaposi's sarcoma or other cancers associated with HIV infection.

PREVENTION

Because there is no vaccine for HIV, the only way people can prevent infection with the virus is to avoid behaviors putting them at risk of infection, such as sharing needles and having unprotected sex.

Many people infected with HIV have no symptoms. Therefore, there is no way of knowing with certainty whether a sexual partner is infected unless he or she has repeatedly tested negative for the virus and has not engaged in any risky behavior. Abstaining from having sex or use male latex condoms or female polyurethane condoms may offer partial protection, during oral, anal, or vaginal sex. Only water-based lubricants should be used with male latex condoms.

Although some laboratory evidence shows that spermicides can kill HIV, researchers have not found that these products can prevent a person from getting HIV.

Recently, NIAID-supported two studies that found adult male medical circumcision reduces a man's risk of acquiring HIV infection by approximately 50 percent. The studies, conducted in Uganda and Kenya, pertain only to heterosexual transmission. As with most prevention strategies, adult male medical circumcision is not completely effective at preventing HIV transmission.

Circumcision will be most effective when it is part of a more complete prevention strategy including the ABCs (Abstinence, Be Faithful, Use Condoms) of HIV prevention.

RESEARCH

NIAID-supported investigators are conducting an abundance of research on all areas of HIV infection, including developing and testing preventive HIV vaccines, prevention strategies, and new treatments for HIV infection and AIDS-associated opportunistic infections. Researchers also are investigating exactly how HIV damages the immune system. This research is identifying new and more effective targets for drugs and vaccines. NIAID-supported investigators also continue to trace how the disease progresses in different people.

Scientists are investigating and testing chemical barriers, such as topical microbicides, that people can use in the vagina or in the rectum during sex to prevent HIV transmission. They also are looking at other ways to prevent transmission, such as controlling STIs, modifying personal behavior, and pre-exposure prophylaxis (PrEP), as well as ways to prevent transmission from mother to child.

LINKS

AIDSinfo
P.O. Box 6303 Rockville, MD 20849-6303
1-800-HIV-0440 (1-800-448-0440) or 301-519-0459 1-888-480-3739 (TTY/TDD)

National Institutes of Health HIV vaccine clinical trials
1-866-833-LIFE (1-866-833-5433).

National Institutes of Health HIV/AIDS clinical trials
1-800-243-7644

NIAID is a component of the National Institutes of Health (NIH), which is an agency of the Department of Health and Human Services. NIAID supports basic and applied research to prevent, diagnose, and treat infectious and immune-mediated illnesses, including HIV/AIDS and other sexually transmitted diseases, illness from potential agents of bioterrorism, tuberculosis, malaria, autoimmune disorders, asthma and allergies.

News releases, fact sheets and other NIAID-related materials are available on the NIAID Web site at http://www.niaid.nih.gov.

Prepared by: Office of Communications and Public Liaison National Institute of Allergy and Infectious Diseases National Institutes of Health Bethesda, MD 20892

Reprinted 08/2008 by:
Industrial-Alliance *Pacific* Life Insurance Company
United States Branch