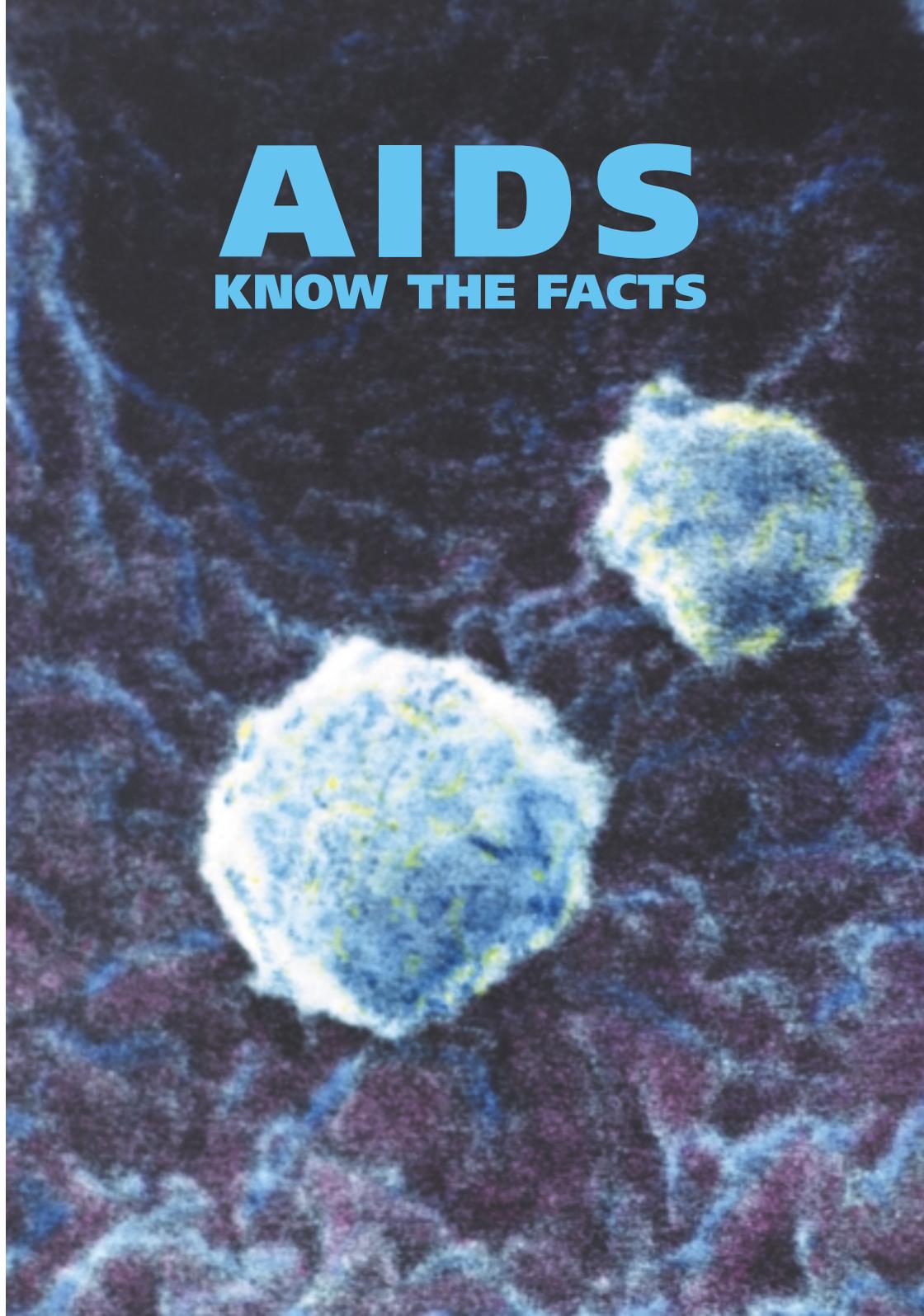


AIDS

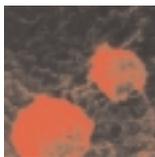
KNOW THE FACTS



AIDS

KNOW THE FACTS

This guide is designed to explain the fundamental scientific aspects of HIV and AIDS. It is not meant to be comprehensive or an academic text. It is an easy to read explanation of the facts, and is intended to be information that can be kept and referred to over time. Readers who are particularly interested in the details should do further reading. At the end of this guide, there is a list of references used. Words in bold are explained in a glossary at the end of the booklet.



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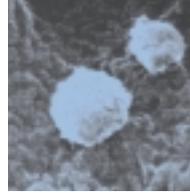
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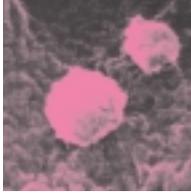


Front cover photograph:
Close-up of isolated HIV viruses budding from cell protrusions of an infected white blood cell.
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what is HIV and what is AIDS?

All people have immune systems, which protect them against disease. If someone becomes infected with HIV (Human Immuno-deficiency Virus) then, in almost every case, over a period of time, the virus destroys his or her immune system. This person is then easily infected by diseases that someone with a healthy immune system can usually fight off.

For most people who are HIV-positive (i.e. infected with HIV) the first few years of the illness are often not life-threatening, but eventually their immune system becomes very weak. As a result, they become so sick that they will die if they don't receive treatment.

It is when a person's immune system has deteriorated so much that they start becoming ill with life-threatening and often unusual diseases that they are said to have **Acquired Immune Deficiency Syndrome**, better known as AIDS. (Many scientists use the terms HIV-disease or severe-HIV, rather than AIDS, but this document uses the term AIDS because it is the most commonly used term to describe people who have become very sick as a result of HIV infection.)

The disease is **acquired** because it is contracted from a source of blood or bodily fluid other than one's own. HIV is transmitted through unprotected

vaginal, anal and possibly oral sex, via infected needles (usually by drug users or health-care workers), via transfusion of infected blood and from mother-to-child during pregnancy, labour, delivery or breast-feeding.

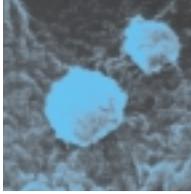
It is called an **immune deficiency** because the immune system of infected people weakens over time. In particular, HIV destroys what are called CD4 cells. These cells are part of the immune system and are the cells that the body uses to defend itself.

A **syndrome** is a collection of signs and symptoms or diseases. AIDS is a syndrome because a whole range of illnesses, referred to as opportunistic infections, are associated with the disease.

People with HIV are much more likely to contract and die of TB (Tuberculosis) than people with healthy immune systems. Diseases such as PCP (a type of lung infection), Oesophageal Thrush (a fungus that grows in an infected person's throat, preventing him or her from swallowing), Kaposi's Sarcoma (a type of cancer) and Cryptococcal Meningitis (a fungus that causes a swelling of the brain lining) are highly unlikely to infect someone who does not have HIV, but they are very common in people with HIV. There are a whole range of illnesses which people with HIV are much more likely to get than people without HIV.

It is possible for people to become sick with symptoms similar to those of AIDS without having HIV, but this is extremely rare. For example people who have to undergo organ transplants are given drugs to suppress their immune systems to prevent the body rejecting the organ. For a period, they can get the same kind of illnesses that occur in people with AIDS.





the cause of AIDS

Extensive scientific analysis and experience with the AIDS epidemic across the globe, in countries of the North and South, have resulted in the vast majority of scientists, doctors and nurses reaching the conclusion that HIV is the cause of AIDS.

Scientific criteria used to determine the cause of a disease

The criteria developed by Sir Bradford-Hill are the core of modern approaches to determining the cause of a disease. HIV as the cause of AIDS meets all of these criteria.

The Sir Bradford-Hill criteria are:

1. The cause must precede the disease.
 2. There must be a strong statistical association between the cause and the disease.
 3. There must be a biologically believable explanation of how the cause results in the disease.
 4. Higher levels of the cause leads to more disease.
- HIV meets all the Bradford-Hill Criteria for determining the cause of a disease.

Criterion 1:

The cause must precede the disease

There have been no cases of HIV infection occurring after a person has got AIDS. In nearly every diagnosed case of AIDS, HIV has been found.

Criterion 2:

There must be a strong statistical association between the cause and the disease

Statistical evidence around the world has shown the association between HIV and AIDS. In a number of studies, people with HIV were shown to be the only ones who developed AIDS. HIV negative people simply do not get AIDS. Immune deficiencies do occur for reasons other than HIV (such as with organ transplants, advanced cancer or malnutrition) but these do not result in a progressive loss of immune cells, which is the pattern observed in AIDS.

Studies conducted all over the world show that nearly every person who has symptoms of AIDS also has the HIV **antibody** in their blood.¹ Here are some examples of the evidence for criteria 1 and 2.

Of 230 179 patients in the United States diagnosed with AIDS, all but 299 tested positive for the HIV antibody. Later analysis showed that 131 of the 299 actually were HIV-positive.² This means that over 99.9% of the people diagnosed with AIDS were HIV positive.

In another study of 8 000 participants, people with HIV were 1 100 times more likely to develop a disease associated with AIDS than someone without HIV. In medical science this is an extremely high level of association between a cause and an effect, demonstrating how highly unlikely it is that there is some cause of AIDS other than HIV.³

The causal relationship between HIV and AIDS is also strongly demonstrated in children. Paediatricians globally are witnessing growing death rates among HIV positive children. This has been scientifically demonstrated



in a study in the Netherlands, in which eleven HIV-positive children were followed over a ten year period. Eight died of AIDS and the other three have experienced a progressive decline in their immune systems.⁴

Criterion 3:

There must be a biologically believable explanation of how the cause results in the disease

The biological mechanism by which HIV causes AIDS is well understood. When the virus enters the human body it infects CD4 cells, also known as T-helper cells. CD4 or T-helper cells are part of the immune system the body uses to defend itself. The HIV virus uses these cells to reproduce and in so doing destroys the CD4 cells. Once enough of the CD4 cells are destroyed, an infected person is likely to fall ill with diseases that are less serious or very rare in people with healthy immune systems.

CD4 cells are a crucial part of the immune system because they direct the other immune system cells. They are often compared to the conductor in an orchestra. Just as an orchestra cannot play music without a conductor, so the immune system cannot function properly without CD4 cells.

Criterion 4:

Higher levels of the cause leads to more disease

Several studies involving follow-up of HIV infected people have shown that the start of AIDS is strongly associated with the number of viruses in the blood. Those with 50-200 copies of the virus per cubic millilitre of blood have long survival times while those with over 100,000 copies show rapid deterioration and faster progression towards sickness and death.



Research in Africa also shows the link between HIV and AIDS

A study in Uganda of 8 833 people of all ages monitored over a period of five years showed that people with HIV were 16 times more likely to die than people without HIV.⁵ Another Ugandan study of 19 983 adults over a period of 20 to 30 months demonstrated that HIV-positive people were 20 times more likely to die than people without HIV.⁶

In South Africa, the hospitalisation rate of children with severe respiratory infections (such as TB) is 6.5 times higher for HIV-positive children.⁷ HIV positive women in a study in King Edward Hospital in Durban, were ten times more likely to have TB than HIV-negative women.⁸ Another study in Durban found that HIV-positive pregnant women were twice as likely to die as HIV-negative women within a year of giving birth.⁹

These and similar African studies show clearly the link between HIV and AIDS.

Furthermore, diseases such as PCP (a type of lung infection) and cryptococcal meningitis, (a fungus that causes swelling of the brain lining) once rare in Africa, are now becoming more common. In South Africa and across the continent, TB rates have risen alarmingly in recent years. A study in Hlabisa, in Kwazulu-Natal has shown that together with a steep rise in HIV infections, the number of people admitted to hospital with TB rose by 360% between 1992 and 1998. Although TB has been very common in South Africa for a long time, in recent years it has begun to disproportionately affect young and middle-aged people. A Gauteng Department of Health study of 28 522 miners from Southern Africa demonstrated that those miners with HIV and TB constituted the overwhelming number of deaths recorded in the study. Of 28 miners who died in the period of the study, 26 were HIV-positive.



Similar studies reaching similar results about the link between HIV and AIDS have been conducted in Tanzania, Malawi, Rwanda, Ivory Coast and the DRC.

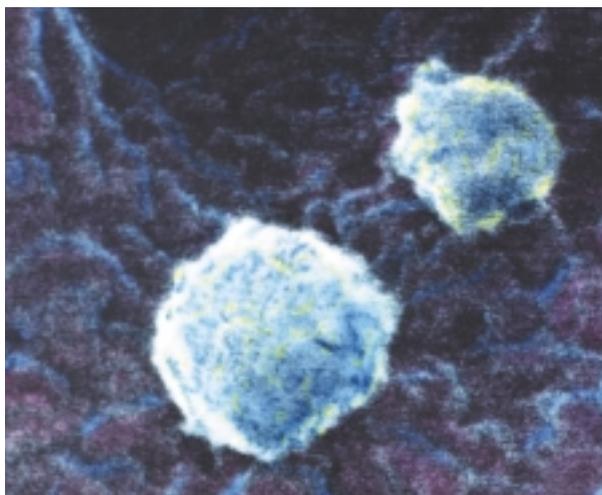
HIV has been isolated and photographed

The Pasteur Institute in France isolated HIV outside of the human body in the 1980s. Many electron micrographs (a method for photographing very small objects) have been taken of HIV (see below).

The link between poverty and AIDS

As is the case with many diseases, poverty makes AIDS worse but it does not cause AIDS. HIV must be present for AIDS to occur. Poverty places people at greater risk of acquiring HIV in many ways.

- Poverty and unemployment force women into sex work and increase relationships of dependency, mak-



Close-up of isolated HIV viruses budding from cell protrusions of an infected white blood cell.

Photomicrograph © 2002 Custom Medical Stock Photo.

ing women vulnerable to coercive and unprotected sex. Single sex hostels, migrant labour, limited health and recreational facilities and lack of access to information all contribute to the spread of AIDS.

- Someone who is HIV positive and poor may not be able to eat well. This may make the person weak and can contribute to the person beginning to get sick with AIDS.
- Poor people with HIV often cannot access the adequate health-care facilities or medicines necessary for staying healthier for a longer period of time.

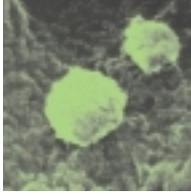
However, this is not the same thing as saying poverty causes AIDS. In the absence of HIV, someone who is poor cannot develop AIDS. On the other hand, someone who is not poor can develop AIDS. Many well-off people have died of AIDS.

Only a person's HIV status can predict whether they will develop AIDS

Many studies have shown that factors such as sexual behaviour and drug abuse do not predict whether a person will get AIDS. The only factor that predicts the development of AIDS is HIV-status. Some people in America who deny that HIV caused AIDS argue that AIDS in the developed world is caused by drug abuse among homosexuals. Yet there is overwhelming evidence against this argument. In Canada 715 gay men were followed for an average of over 8 years. Every person who developed AIDS in this sample had HIV. Among the HIV-negative men in the group there were some who frequently used illegal drugs. None contracted AIDS.

There are many other compelling arguments that HIV causes AIDS, including some based on studies done in the developing world and Africa.





t testing for HIV

What are the different types of HIV tests?

There are a number of different HIV tests. Some test for the HIV **antibody**, while other more expensive ones detect the actual virus directly, as well as the amount of virus (e.g. the PCR test).

The antibody tests are used most frequently and can be measured using different techniques such as the ELISA, EIA and Western Blot tests. The ELISA test is used most. There are also antibody tests that can measure whether someone has been recently infected with HIV or whether a person has a long-standing infection.

HIV testing can be done using blood, urine, semen, vaginal secretions or sputum. The results from the standard ELISA are usually only available a few days later as the tests need to be conducted in laboratories with specialized equipment. A rapid test kit is now available that can be used easily and provide results within 15 minutes.¹⁰

All positive results are double-checked

It is standard practice in South Africa to confirm an HIV-positive result using a different testing product from that used in the first test. (Both tests are done on the same blood sample — it is not necessary to go back for a second test.) This is thought necessary because of the psychological implications of being incorrectly diagnosed with a life-threatening disease. When someone is tested for HIV, they should be given pre-test and post-test counselling.

How accurate are HIV tests?

Numerous studies conducted throughout the world show that the HIV tests commonly used in South Africa are very accurate. The ELISA test is considered the standard antibody test. When it is used together with a second test, the probability of an error is very low.

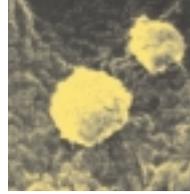
One of the most commonly used rapid tests in South Africa is called *Determine*. This test correctly identified all 100 HIV-positive and 66 HIV-negative blood samples in a study conducted in Honduras and the Dominican Republic. All reputable laboratories that do HIV testing in South Africa are properly accredited and meet rigorous standards through having the labs visited by accreditation bodies and participating in anonymous quality assurance checks. All test kits have internal controls built in to ensure that the test kit is working.

There are two additional things to consider with regard to HIV tests:

- When a person becomes infected, the virus is usually not detectable in their blood for the first few weeks. If tested during this period, the HIV tests might indicate that the person is HIV-negative. The time from infection until a positive diagnosis is called the window period.

- Babies born to HIV-positive mothers are usually born with HIV antibodies, irrespective of whether or not they are infected with the virus. These antibodies come from the mother. If the child does not actually have HIV, these antibodies clear out of the body over a period of time. This means that an HIV antibody test is not considered accurate for the first 18 months after birth. However, there are more expensive tests which check directly for the virus (such as the PCR test). These tests are accurate and can be used a few weeks after birth.

There is no scientific basis for the view that HIV tests are not accurate in Africa. African blood types are *not* different to the blood types in Western countries in which these tests have been developed, TB *does not* interfere with the accuracy of HIV tests and South Africa *does* have the infrastructure to ensure that laboratories produce reliable results.



how serious is the HIV epidemic in South Africa?

South Africa has a sophisticated infrastructure for surveying the extent of HIV throughout the country. As a result, reasonably good estimates can be made of the extent of the epidemic. No one knows exactly how many South Africans are infected with HIV as not every South African is tested. There is however overwhelming evidence that the epidemic is very serious and that millions of people will eventually die of AIDS, and more people will become infected if there is no effective intervention.

Every year the government conducts a survey in public antenatal clinics. This survey determines the percentage of pregnant women attending these clinics who are HIV-positive. In 2001, nearly 25% of pregnant women were found to be HIV-positive.

The Department of Health uses the antenatal clinic survey data to estimate the number of people infected with HIV in South Africa. The estimates are that 4.74 million South Africans were infected with HIV at the end of 2001.

In addition to this information, mathematical models have been constructed that estimate the number of people with HIV and AIDS throughout the whole country. It is true that these models make many assumptions and there is a margin of error in their results. However, even taking into account

large margins of error, the models provide evidence that the extent of the problem is serious.

A commonly used model is the ASSA 2000, developed by the Actuarial Society of South Africa.¹¹

Using this model estimations are that:

- HIV is the single largest cause of death.
- In two years, if nothing is done, more people will die of AIDS in South Africa than all other causes of death added together.
- Life-expectancy will fall to 41 years from over 60 years. (As a comparison, Cuba, a very poor country, has a life-expectancy of well over 70 years.)
- The number of double-orphans (i.e. children who have lost both parents) due to AIDS will rise to over two million over the next twelve years, in the absence of any intervention.
- If antiretroviral treatment became available on a wider scale (i.e. in the public health-care system), the number of orphans could be reduced by about a million.¹²

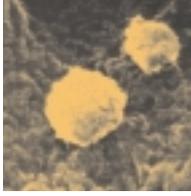
Researchers at the Medical Research Council¹³ have found that deaths have increased substantially over the last decade, especially the last few years. This is due to increased deaths among young and middle-aged adults, especially women. The researchers provide convincing arguments that the only reasonable explanation for this is AIDS. They conclude that AIDS is the biggest single cause of death in South Africa.

What constitutes a comprehensive response to the AIDS epidemic?

A comprehensive approach to AIDS — shown to be effective in the control of AIDS epidemics worldwide — involves prevention and promotion programmes (including inter alia, social and behaviour change programmes

and condom distribution*), poverty alleviation, voluntary testing and counselling, positive living programmes, mother-to-child transmission prevention programmes, the treatment of sexually transmitted diseases and opportunistic infections, home-based care and support, antiretroviral treatment.

* A special review panel led by the National Institute of Health in the USA found an 85% decrease in risk of HIV transmission among consistent condom users versus non-users.¹⁴



Opportunistic infections

What are opportunistic infections?

HIV gradually destroys the immune systems of infected people. Opportunistic infections are the diseases that take advantage of an HIV-positive person's weak immune system, making them ill. Some of these are infections which only affect people with HIV (with some very rare exceptions), while others are more common infections which are more serious in people with HIV. These are the diseases that actually cause the death of most people with AIDS. In a small minority of cases HIV itself directly causes death.

People with HIV often remain well and show no symptoms for many years after they have become infected. Living healthily — eating well, exercising, avoiding cigarettes and alcohol — can help prevent opportunistic infections. HIV positive people are advised to take drugs to protect against TB and other opportunistic diseases. However, most people only learn about their HIV status after starting to show signs of these infections.

The four stages of HIV infection

The World Health Organisation divides HIV infection into four stages. This system should be seen as a

guide only. Each stage is characterised by more serious and frequent opportunistic infections than the previous one.

Stage one: There are few or no signs that a person is infected. Swollen lymph glands are common, but these are not usually cause for alarm.

Stage two: Typically characterised by minor skin problems, head or chest colds and weight loss. Herpes zoster (also known as shingles) often occurs in this stage.

Stage three: More serious problems begin to occur such as profound weight loss, chronic diarrhoea, fever, oral thrush (a fungus in the mouth), vaginal thrush, pneumonia (lung infection) and TB.

Stage four: Very serious diseases, some of which are seldom found in HIV-negative people, occur. These include a lung infection known as pneumocystis carinii pneumonia, oesophageal thrush (a fungal infection in the throat), infections of the brain such as toxoplasmosis and cryptococcal meningitis, severe diarrhoea, profound weight loss and cancers such as Karposi's Sarcoma.

Can opportunistic infections be treated?

Most opportunistic infections can be treated. However, in the later stages of AIDS, the immune system usually becomes so weak that medicines for treating the opportunistic infections no longer work. For most people, antiretroviral therapy beginning even as late as Stage Three or Four can reverse the damage done to the immune system by HIV and thereby reduce the frequency and severity of opportunistic diseases.

Common opportunistic infections

Tuberculosis

Tuberculosis (TB) is caused by a germ that spreads through the air when a person who has the disease coughs, sneezes or breathes. So it is easy for the germ to spread. However, a healthy person, with a strong immune system is unlikely to develop the TB disease. Poor people who are unable to have a healthy diet and all people with HIV are at greater risk of becoming sick with TB disease. It is also the most common cause of death among people with AIDS in South Africa.

TB can be treated even in people who are HIV positive.

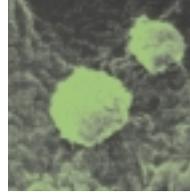
Thrush

Thrush is a fungus which can grow in the vagina, mouth or throat. Its scientific name is Candidiasis. Thrush in the mouth and throat can prevent people from eating and is therefore very serious. Good nutrition plays an important role in keeping the immune system strong, so diseases which affect a person's ability to eat or swallow are particularly dangerous. A number of medicines are available to treat thrush, one of which is Diflucan, currently available free of charge in South African clinics and hospitals.

Infections with germs causing diarrhoea

In Southern Africa, almost all people with AIDS develop diarrhoea at some point. A person has diarrhoea if they have two or more loose stools a day. It can last for days or even months. With severe diarrhoea people with AIDS can lose several litres of fluid a day. Common everyday infections that cause minor diarrhoea in people without AIDS can cause severe diarrhoea in people with AIDS.

Doctors prescribe drugs to treat diarrhoea according to the type of germ responsible for causing it. It is also important to drink a lot of fluid to prevent dehydration.



antiretroviral medicines

What are antiretroviral medicines?

These are medicines that attempt to prevent the HIV virus from reproducing inside the body, allowing the immune system to recover. AZT and nevirapine are commonly spoken of but there are currently 14 different kinds of antiretroviral medicines, and many more are being researched. There are three main purposes for which antiretroviral (ARV) medicines are used:

- To reduce the risk of a woman transmitting HIV to her newborn child. This is commonly referred to as Mother-to-Child Transmission (MTCT) Prevention. (See page 30)
- To reduce the risk of people who have been exposed to HIV through occupational injuries or rape, from contracting it. This is known as Post-Exposure Prophylaxis (PEP). (See page 28.)
- People who are infected with HIV can be treated with antiretroviral medicines in order to stay healthier and live longer. This involves taking three or more different antiretroviral medicines on a daily basis. This is called triple-drug therapy, combination therapy or Highly Active Antiretroviral Therapy (HAART). The different drugs work together to tackle HIV in different ways. The medicines must be taken for life.



Although HIV cannot be cured, through HAART, it is becoming a manageable, chronic disease similar to diabetes or high blood pressure (hypertension).

Are ARVs safe and effective?

ARVs for PEP and MTCT: Many studies have shown that the short course of ARVs needed to reduce the risk of getting HIV from rape, occupational injury or from mother to child is effective and that side effects are uncommon and can be managed with proper monitoring. There are side effects to all medicines, including over the counter headache tablets.

HAART: After over 15 years of research there is strong agreement in the medical world that antiretroviral drugs used to treat people who are already HIV positive, are effective in slowing down the development of AIDS. HAART is used extensively to treat AIDS in the United States, Brazil and Europe. In South Africa, it is estimated that over 20 000 people now use antiretroviral therapy through the private sector, drug trials and government pilot projects. Most drugs can have serious side-effects, including drugs that you can get over the counter at pharmacists. Even paracetamol if taken in large quantities can be fatal. Antiretrovirals are no exception. It is therefore crucial that people on HAART are monitored for side-effects. In most cases where serious side-effects occur, an alternative combination of drugs, which does not cause the side-effects, can be found.

As a comparison, HAART is much more successful at treating AIDS than chemotherapy is at treating cancer, but chemotherapy often has far more serious side effects than HAART. When one considers that for people with AIDS the alternative is death, the benefit of HAART far outweighs the risks.

What is resistance? Is it a problem?

When a medicine is used to destroy a virus, the virus often mutates (changes its form or appearance) and then the medicine is no longer effective against it. The virus is said to have developed a resistance to the medicine. When this happens, the antiretroviral drugs that a patient is taking become much less effective and the virus begins to destroy the immune system again. This happens with the use of most medicines used to fight germs, including antiretrovirals.

Patients on HAART treatment might need to change to a different set of antiretroviral drugs when resistance occurs. Eventually a patient might run out of antiretrovirals that he or she can successfully use. In most people who take their drugs correctly, this situation should only occur after many years and even then all options are not necessarily closed off, but fighting the disease does become much harder.

Resistance is a serious problem:

- It reduces treatment options for people with HIV.
- Resistant strains of the virus can be passed on to other people, thereby limiting their treatment options.

Antiretrovirals have an important role to play in a country's response to AIDS despite problems with resistance. If people are not treated, they are likely to die of AIDS irrespective of whether or not they have a resistant strain of HIV. This is similar to the case of TB where despite some types of TB being resistant to some types of drugs, TB patients continue to receive treatment.

Do antiretrovirals work?

There is overwhelming evidence that antiretroviral drugs have reduced the number of people with HIV dying of

AIDS in the US, Europe and Brazil. A breakthrough study¹⁵ on the success of triple-drug therapy in 1998 examined 1 255 patients in the United States. It showed that irrespective of race, sex, age or the manner in which HIV was contracted, antiretroviral medicines significantly reduced the number of deaths and diseases among HIV-positive people. There was an improvement of over 70% compared to those using no drugs. Many studies since then have confirmed similar results. A study of 4 270 HIV-positive people in Europe found that the death-rate fell by over 80% after the introduction of HAART.¹⁶

The Medecins Sans Frontieres pilot project in Khayelitsha found that the incidence of opportunistic infections decreased more than five times as a consequence of HAART.¹⁷

Do antiretroviral drugs work in developing countries?

Brazil is a developing country that has a policy of providing antiretroviral medicines to people with AIDS. The Brazilian government estimates that deaths among HIV-positive people have fallen by over 50% since the introduction of HAART.¹⁸ A study in Chile, also a developing country, shows similar results.¹⁹

In South Africa, clear evidence has emerged that HAART works. HAART programmes at Somerset Hospital, Site B clinic in Khayelitsha, Chris Hani Baragwanath Hospital and many private practices are demonstrating that HAART is effective, even in poor areas. A study at Somerset Hospital has demonstrated that people with HIV are far less likely to get TB once they begin taking HAART. This is an extremely important finding because TB is the opportunistic infection responsible for the most deaths of HIV-positive people in South Africa.

Do HAART patients have to take pills at the same time everyday for the rest of their lives?

At present people who go onto HAART have to do so for life. This is because although HAART keeps down the level of HIV in the body, it is not a cure and cannot eliminate HIV entirely from the body.

Patients who take their antiretrovirals on time everyday do better than patients who do not.

Is it possible for poor people living in under-resourced areas to use HAART correctly?

Yes. A study done at Somerset Hospital that included many poor people living in poor areas showed that South Africans take their medicines as well as people in developed countries. A study conducted in Haiti has also shown that it is possible for people in poor environments to take part in HAART programmes. Also, new HAART pills are constantly being developed which require taking fewer pills less often, making it easier for patients to keep to the programme. However, as with treatment programmes anywhere, education is needed to support the correct use of antiretrovirals.

Do all people with HIV need to use antiretrovirals?

No. HAART is only necessary for people whose CD4 count is below 200, or for people who have AIDS defining illnesses. On average people can live without HAART for about eight years after contracting HIV, although this varies considerably between individuals. Most people

with HIV, though not all, eventually need to go onto HAART in order to continue living a healthy life.

Is it true that scientific thinking around HAART changes all the time?

The science of how and when to use antiretrovirals is improving all the time. The HIV/AIDS Treatment Information Service in the United States publishes definitive guidelines on how HAART should be used.²⁰ It is important to understand that the changes made to these guidelines are improvements. They do not question the fact that HAART is effective or safe if properly monitored.

Are antiretrovirals still in the experimental stage?

No. The safety and effectiveness of antiretroviral drugs has been well established through trials and research over the past 15 years. Antiretroviral drugs are registered by all major drug control bodies around the world. Studies such as that being conducted by Medecins Sans Frontieres in the Western Cape, focus on the operational issues concerned with running antiretroviral programmes in poor areas. Such studies will provide valuable lessons for administering future antiretroviral programmes in Southern Africa.

What other issues must be taken into account in a treatment programme?

Health service delivery infrastructure

Health delivery infrastructure is important to ensure a treatment programme is effective. Some public hospi-

tals and clinics are equipped to implement HAART, but many are not. A successful programme must have the following components: adequately trained nurses and counsellors, a counselling facility, a reliable drug supply, and reliable communication with a laboratory that can perform the tests essential for monitoring patients on HAART. Developing HIV services may help to improve the health system as a whole because of the need to strengthen services in some of the poorest and most disadvantaged areas of the country where many people need HIV care.

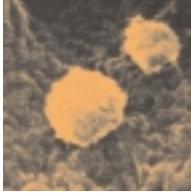
The cost of HAART drugs and monitoring

ARV drugs used for HAART are expensive. If these prices are lowered sufficiently, these life saving drugs could be made available to all South Africans, not just the well off or those on medical aids.

HAART patients must undergo regular monitoring tests. These include CD4 counts which monitor a patient's progress as well as various blood tests designed to identify serious side-effects. These tests are becoming more affordable. However, the tests used to detect the amount of virus in the patient's blood (known as viral load tests) remains very expensive. Viral load tests are useful for determining the extent to which the antiretroviral medicines have suppressed the virus in the patient's body.

A treatment programme is an important part of a country's comprehensive response to the HIV epidemic. However, the cost of drug treatment and monitoring as well as health service delivery infrastructure are issues that need to be addressed as part of a roll out of any treatment plan.





preventing HIV infection after occupational injuries and rape

Occupational injuries and HIV²¹

Needle-stick injuries often occur among health-care workers. If the needle has been exposed to the blood (or other bodily fluids) of someone who is HIV-positive, there is a small but definite risk that the virus might be transferred to the health-care worker. Administering antiretroviral medicines to a person who has been exposed to HIV to prevent transmission of the disease is known as PEP (Post Exposure Prophylaxis).

A 1997 US study of a small number of cases, found that the risk of HIV infection can be reduced by approximately 81% when taking the antiretroviral medicine AZT.²² Experiments performed on animals also suggest that PEP is effective.

Research conducted in King Edward Hospital in Durban, has shown that not a single transmission has taken place when a combination of antiretroviral drugs was used. The balance of evidence indicates that providing antiretroviral medicines to health-care workers who have experienced needle-stick injuries is potentially life-saving.

Why does PEP work?

There is a short period from when a person is exposed to HIV to the time that the virus has multiplied or reproduced sufficiently in the body to have systematically infected the person. During this period, antiretroviral drugs can stop the virus from multiplying. This eliminates the virus from the exposed person's body.

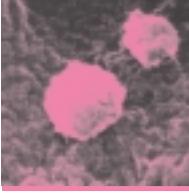
Rape and HIV transmission²³

Although it is difficult to estimate precisely, the risk of HIV infection from rape is significant. Gang rape increases the risk. It is also difficult to estimate how effective PEP is after rape, but research indicates that PEP can reduce the risk of contracting HIV. One of the most compelling arguments for providing PEP in South Africa comes from research performed in Sunninghill Clinic in Johannesburg. Over 1 000 cases of people who were given AZT within 72 hours of being raped were monitored. None contracted HIV.

It is government policy that PEP be made available in public hospitals and clinics free of charge to all rape survivors.

Is PEP guaranteed to work?

No. The risk of transmission after taking PEP is low, but there are at least 21 recorded cases of PEP failing to prevent transmission for occupational injuries.²⁴



Preventing mother-to-child transmission of HIV

Will a child born to an HIV-positive mother contract HIV?

Various studies show that about 30 to 35 out of every 100 children born to HIV-positive women, get HIV from their mothers. This can happen either during pregnancy, labour, delivery or breast-feeding. Most of these transmissions occur during labour and delivery. Programmes to prevent mother-to-child transmission of HIV have been conducted in many countries, including Uganda, Ivory Coast, South Africa, Thailand, Botswana, Brazil and the United States. These programmes have been successful at reducing the number of HIV infections in babies born to HIV-positive women. In Europe, North America and parts of Brazil, the HIV epidemic in newborns and infants has been brought under control through these programmes.

How is mother-to-child transmission prevented?

A study in Uganda, known as HIVNET 012, demonstrated that the risk of transmission of HIV from mother to child can be significantly reduced (by

about 47%) using an antiretroviral medicine called Nevirapine. At the onset of labour the mother is given a Nevirapine pill and the newborn child is also given a dose of Nevirapine in syrup format. It is only effective at reducing transmission during labour and delivery. It does not prevent transmissions that occur during pregnancy or through breast-milk. Nevirapine is what is used in South Africa.

Is Nevirapine safe?²⁵

When used for MTCT prevention, Nevirapine has been shown to be both safe and effective. Thousands of women and children have gone through MTCT prevention programmes using Nevirapine. No serious side-effects due to Nevirapine have been reported in mother or child in the HIVNET 012 study in Uganda, nor in the SAINT (South African Interpartum Nevirapine Trial) trials in South Africa. The pilot mother-to-child transmission projects in South Africa and programmes in other parts of Africa, Asia and Latin America have also shown Nevirapine to be safe and effective.

Often there is confusion over the use of Nevirapine for MTCT prevention and long-term use of Nevirapine for treating someone with HIV (as part of HAART). With long-term use, Nevirapine can have side-effects. However, this is not the case with the single dose of Nevirapine to mother and child in an MTCT prevention programme.

What were the problems in the Ugandan trial which demonstrated the efficacy of Nevirapine?

The Ugandan HIVNET 012 trial was conducted between 1997 and 1999 in order to find an effective method of



preventing mother-to-child transmission in a developing world setting. Recently Boehringer Ingelheim (BI), a manufacturer of Nevirapine and the patent-holder of the medicine, applied to the American based Food and Drug Administration (FDA) to register Nevirapine for mother-to-child transmission prevention in the United States. FDA approval would mean that BI could advertise that Nevirapine reduces mother-to-child transmission prevention in the United States. The FDA indicated that there were unresolved issues with the documentation of the HIVNET 012 trial in Uganda. Therefore BI decided to withdraw their application to the FDA until the documentation issues are rectified. This does not mean that Nevirapine cannot be used for mother-to-child transmission prevention in the United States.

The scientific institute that sponsored and conducted the trial, the National Institute of Health, as well as the World Health Organisation, the Centre for Disease Control, the FDA and BI have all released statements indicating that these documentation issues are of an administrative nature and do not negate the findings of HIVNET 012 that Nevirapine is safe and effective. The problem with the documentation is that the trial was conducted a few years before BI's application and the FDA requires that the hospital records of the patients who participated in HIVNET 012 must be matched against the records kept by the scientists who conducted the trial. Because of the retrospective nature of BI's application and the methodology for recording patient visits used at the Ugandan hospital, this is difficult to do. However, no evidence has arisen that the records kept by the scientists are inaccurate or fraudulent in any way.

What feeding options are available to a child born to an HIV-positive woman?²⁶

Breast-feeding increases the risk of transmission of HIV from mother-to-child. Using formula milk instead of breast-milk can solve this problem but lack of access to clean water to mix the milk or to clean feeding bottles increases the risk of children contracting infections that can also be fatal. The World Health Organisation recommends that women be counselled on their feeding options. The choice to use formula-milk or to breastfeed should be theirs to make, but they should be fully informed of all the risks and advantages associated with each option. They should also be provided with adequate support for their choice.

It is likely that if women take antiretroviral medicines while they breastfeed, then the risk of transmission is lower. But few women in South Africa have access to this choice. Research into finding cheaper antiretroviral regimens that women can use while breastfeeding is being conducted in South Africa. Formula milk is a viable option for women who have reliable access to clean water. For women who do not have access to clean water or who choose not to use formula milk, exclusive breast-feeding (i.e. the baby is fed no other foods) with abrupt weaning at six months reduces the risk of transmission.

What else does a mother-to-child transmission prevention programme consist of?

Besides the provision of counselling on breastfeeding options, formula milk (if mother chooses) and antiretroviral treatment such as Nevirapine, an MTCT prevention programme must include voluntary counselling and test-

ing for women when they attend their antenatal clinics, and women should be offered the option of termination of pregnancy. Also, after the baby is born, it will need to be tested to determine if it has contracted HIV. Most facilities in the public health sector offering MTCT prevention use antibody tests to determine the HIV status of the infant. Infants therefore have to be tested at 9 months and possibly even again at 18 months (see page 14). A more expensive PCR test can be used to accurately determine the infant's status after a few weeks.

Delivery procedures that take into account the woman's HIV status and reduce the amount of blood and other bodily fluids with HIV during labour also reduce the risk of transmission.

Does MTCT prevention always work?

No. Hardly anything in medicine is guaranteed to work every time. A Nevirapine and formula-milk based MTCT prevention programme will probably reduce the MTCT rate from 30 to 35% to about 12 to 15%.

Are the pilot sites testing the safety and efficacy of Nevirapine?

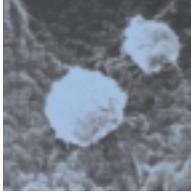
The South African MTCT prevention pilot sites are NOT testing the safety and efficacy of Nevirapine. They have been implemented to determine the operational issues involved in running an MTCT prevention programme. The safety and efficacy of Nevirapine for MTCT prevention have been demonstrated already.

Is Drug Resistance a problem with MTCT prevention?²⁷

(For an explanation of resistance, see page 23.)

Some women who use Nevirapine for MTCT prevention develop resistance to the drug. Currently, this is estimated to affect about 30% of women. The resistance does not affect the infant and wanes in the mother after 7-9 months, probably reversing the resistance. The resistant virus that develops is no more harmful than the original virus that was in the women's body. If anything the balance of evidence shows that it is less effective at destroying the immune system than the original virus. However, it is possible, though not clear, that women who develop resistance to Nevirapine may reduce the treatment options available to the patient in future, should she be able to access antiretroviral therapy. It might mean that Nevirapine will not be an effective medicine for treating her. Nevertheless, other effective antiretroviral treatment options remain open. It is also worth noting that about 30% of South Africans with TB-disease are resistant to INH, yet it is still used as part of the combination of drugs used to treat people with TB.

Medical consensus is that the benefits of MTCT programmes outweigh concerns around resistance to nevirapine.



G glossary

Antibody A cell developed by the body's immune system to fight against a virus, germ or foreign body.

Antiretrovirals Drugs that fight against retroviruses, such as HIV.

Transmission When HIV is passed over from one person to another.

Exposure When a person has come into contact with HIV we say they have been exposed to it.

Prophylaxis Medicines taken to prevent a disease occurring.

Needle-stick injury When a health worker is pricked with a needle in the course of his or her work.

Epidemic When a disease spreads rapidly in a community or country and affects many people.

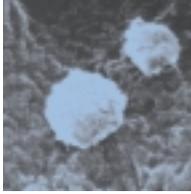
Acquired Something that you get that is not your own. AIDS is "acquired" because it is contracted from a source of blood or bodily fluid other than one's own.

Immune The body's system that fights against infection and disease.

Deficiency Something that is absent or lacking. AIDS is called an immune deficiency because the immune system of infected people deteriorates over time.

Syndrome A collection of signs and symptoms or diseases.

AIDS is a syndrome because a whole range of illnesses, referred to as opportunistic infections, are associated with the disease.

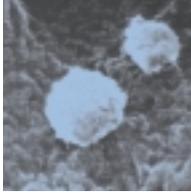


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