

ANTIRETROVIRAL TREATMENT

What is ART and ARV?

ART is a short form for Antiretroviral Therapy (or Treatment). Antiretroviral therapy is a treatment consisting of a combination of drugs which work against HIV by slowing down the reproduction of HIV in the body, reducing the viral load and repairing damage to the immune system. These drugs are often referred to as antiretrovirals (ARV) that is anti-HIV drugs. Treatment with these combinations of drugs is also known as Highly Active Antiretroviral Therapy (HAART).

Since when do we have ART?

In March 1987, AZT (Zidovudine) was first introduced in the USA as the first Antiretroviral agent, but was not very effective. In 1996 a combination of drugs was introduced and the era of HAART began, resulting in big improvements in the health and well-being of HIV patients.

What types and classes of ARVs are there?

Currently, there are about 20 approved types of Antiretroviral drugs in the world and more will be developed in the future. Four different types of ARVs are now available; most of the different ARVs are available in Care and Treatment Centres (CTC) and normally a combination of three drugs is prescribed.

In Tanzania, ARVs were introduced free-of-charge by the government in 2004 and, by July 2008, almost 170,000 people were receiving the drugs.

At what stage should a person who is HIV positive be put on ART?

In order to determine whether an HIV positive person should start ART, the patient is clinically assessed. The assessment considers the clinical staging according to WHO guidelines and CD4 count, full blood picture, and renal and liver function test (For detailed information on CD4 see next question). According to the national Guidelines on ART, an adult or adolescent is put on medication when:

- confirmed HIV positive AND
- CD4 count of <200 cells/mm³, regardless of WHO clinical stage, OR
- WHO clinical stage III with CD4 count of <350 cells/mm³, OR
- WHO clinical stage 4, regardless of the CD4 count. Pregnant women are put on medication when:
 - in WHO stage IV disease, regardless of CD4 count,
 - in WHO stage III and CD4 less than 350 cells/mm³,
 - the CD4 cell count is less than 200 cells/mm³.

In general, the lower the CD4 cell count and the higher the viral load, the higher the risk of AIDS and the more urgent the need for treatment. If a person is found eligible national guidelines give the recommendations on the respective first line ART for

adults, children, pregnant women and those who might have children and people who are also treated for TB.

What is a CD4 cell and what is a CD4 cell count?

CD4 cells are a type of white blood cell. They are an important part of the immune system. The HIV attacks these CD4 cells and slowly destroys them, eventually leading to weaker immune system. The lower the CD4 cell count, the more likely the person will get sick. The CD4 cell count is a key measure of the strength of the immune system.

What factors influence CD4 cell count?

The CD4 cell count varies: time of day, nutrition status, fatigue, and stress can influence CD4 cell count. That is why it is important to always eat well and rest well (as described in the section HIV and Nutrition). For those going for repeated tests for CD4 cell count, it is best to have the tests taken at the same time of the day for each CD4 cell test. Infections and vaccines can have an impact on CD4 cell counts as well. Don't check your CD4 cells until a couple of weeks after you recover from an infection or after a vaccination.

What is PEP?

Post-Exposure Prophylaxis (PEP) is the administration of ARV drugs as a prophylaxis to an HIV-negative individual who has been exposed to body fluids of a (suspected) HIV positive person (e.g. through rape, medical injury). At a hospital the risk of exposure is thoroughly discussed and the person is then informed about effects and risks of PEP. PEP should be administered within 72 hours after the risky exposure. If a person decides to take medicine he or she is administered two or three antiretroviral drugs for 28 days.

What procedures need to be followed by a person to get ARV drugs?

For a person to get ARV drugs, he or she must go to a Care and Treatment Clinic (i.e., a hospital that provides ARV). Usually, during VCT referral is made to the nearest facility that provides ARV.

In that clinic a complete medical history, physical examination, and laboratory evaluation will be made. If the person is found eligible for ART, then the correct drug and dosage will be prescribed. He or she will also be advised on how to detect side effects and what to do in case they occur. Advice on nutrition, drug adherence and resistance will also be given.

How many times a day or a week do you have to take ARV drugs and who prescribes them?

The number of times ARV drugs have to be taken per day varies with the patient and his/her individual drug therapy. One patient may take a combination drug once per day, others may take combinations of two or three drugs several times a day. The

national policy on care and treatment stipulates that a trained medical doctor is responsible for prescribing these drugs and monitoring drug tolerance.

Do ARV drugs expire?

ARVs can expire just like any other drugs and they also have special requirements for storage. Since the drugs are taken on a daily basis, one should always ask the nurse or pharmacist for advice on storage.

Why TB is treated first when a person has TB, is HIV infected and is eligible for ART?

Tuberculosis infection is a common entry point for care of HIV-infected person. Problems may occur when TB and HIV are treated in parallel. TB treatment is normally given priority, but depending on the severity of the HIV infection, onset of ART may be delayed or ART drugs modified for parallel treatment of HIV and TB. Several anti-TB regimens can be administered with effective ARV treatment in HIV-infected persons and some cannot, for example, Rifampicin (a drug used for TB treatment) should not be given with Nevirapin.

Are there ARVs for HIV-positive mothers?

ARV drugs can be administered during pregnancy or at the time of delivery. They are safe for the mother and the baby and effective in reducing transmission. In the health facility, the appropriate drug for pregnant mothers is prescribed.

Can HIV-positive children also take ARV drugs? And do they use the same dosage as adults?

Children can also take ARVs, but since the HIV infection is different and their bodies are different from adults, the dosage and the combination of drugs are different. Yet ART will reduce mortality and morbidity in children and adults alike. Recommended first line treatment for children below three years of age children is Zidovudine, Lamivudine plus Nevirapine.

How does one use ARV drugs and for how long?

It is important to know that different drugs have different rules. Some drugs may be taken only once a day, while other drugs must be taken two or three times a day. ART is a life-long treatment for all patients, but the drug regimen varies from one patient to the other. It is important to know which drug goes with which rule, and each patient should know the following points about his/her ART:

- How many pills of each different medicine am I supposed to take at a time?
- How many times a day am I supposed to take each medicine and when do I take them?
- What are the food requirements for the medicine?
- What should I do if I forget to take the medicine?

In Tanzania there are several fixed-dose combinations available for first line treatment that are administered in different dosages according to body weight (the boundary is usually 60 kg for higher or lower dosages). Combination drug means

that several drugs have to be taken every day, e.g., “Trimune” consists of three drugs: two pills are taken twice a day, and one is taken at night on an empty stomach.

What are the benefits of ART and what happens if a patient stops taking the drugs?

ARV drugs help the body to fight HIV by slowing down the reproduction or multiplication of HIV in the body, reducing the viral load and repairing damage to the immune system.

If a patient stops using ARV drugs, the HI virus will multiply very fast and increase in the body and damage the body’s immune system, making the person more vulnerable for infections.

What can be done if a patient on ART misses the time when he/she is supposed to take the drugs?

When a person on ART forgets to take the drugs, it is recommended for most antiretroviral drugs to then take the drug as soon as possible. If it is already time for the next dosage, then skip the one dose and continue with the next. **Double dosage should not be taken.**

Is it possible for a patient on ART to stop taking the drugs once the immune system improves?

It is not possible for patient on ART to stop taking the drugs once the CD4 cell count increases. Even if the viral load is below detection and CD4 cells have increased significantly, HIV is still in the body and multiplication can continue.

Can ARV drugs or traditional medicine cure AIDS?

There is no drug or traditional medicine that can cure AIDS. Drugs inhibit the viral multiplication, but the HI virus remains in some parts of the body. Some traditional medicines have been found to increase CD4 cell count, but modern ARVs are more effective when compared to traditional medicine. The only reported difference by users is that the herbal medicines had fewer side effects. Also some herbal medicines have been quite effective in treating some AIDS-related illnesses.

What is the effect when both ARV and traditional medicine are taken together?

The worst effect that can occur is drug interaction and suppression of the effect of the drug. The ARVs are then no longer effective. It is strongly recommended not to mix the two.

For how long can a patient on ARV drugs live?

Provided that ARVs are taken in a timely and regular manner, ART can reduce the viral load for many years or even decades.

The current ARVs have been on the market for about ten years and long-term experience and research is not yet available. With correct treatment HIV and AIDS is a manageable condition and no longer a deadly disease.

What are the possible side effects that require change or discontinuation of ART?

Not all side-effects require a change in drugs or discontinuation; for example, nausea, diarrhea and rash are fairly normal at the beginning of therapy for certain drugs. They normally disappear after some time. But certain adverse drug effects do require change of drug regimen, for example:

- Severe diarrhea that persists despite medication, even after several weeks.
- Severe nausea that persists despite medication and requires continuous treatment or leads to significant weight loss.
- Disease conditions such as polyneuropathy, severe anemia, muscular weakness, pancreatitis, lactic acidosis, severe allergies with involvement of a mucous membrane, renal failure, hepatotoxicity and jaundice.

When should ART be stopped?

ART is a lifelong treatment. A patient on ART should not decide on his/her own to stop

ART. The decision should be made together with the doctor at the hospital or CTC clinic after doctor and patient have discussed the clinical, immunological and virological consequences.

When a patient on ARV drugs is vomiting, what alternative treatment is available?

Nausea and vomiting are very common side effects, especially in the first few weeks after starting ART. Most ARVs can be taken with a full meal in order to avoid nausea. If drugs have to be taken on an empty stomach, small amounts of non-fatty food can be taken with the drug. The doctor can also prescribe anti-nausea drugs.

What should be done if ARV drugs cause side effects, especially of the skin?

Many people on ART report skin rash soon after starting the therapy. This is an allergic reaction to the HIV therapy, sometimes occurring together with fever or fatigue. Patients are advised to report to the clinic when these symptoms appear to assess the severity and cause of the rash and to get medication if necessary.

Why do ARVs affect some people by changing the shape or size of their bodies, e.g., breasts or buttocks?

Some people on ART may experience a change in fat distribution of the body. For example, loss of fat in the face, arms, buttocks and legs, and, at the other extreme, enlarged breasts and bellies, along with buffalo humps (fat at the base of the neck). The causes are not yet fully understood. Such a body fat redistribution develops over time. If recognized early, through regular check-ups, a doctor can decide on changes in drug regimen.

Why do some people experience side effects soon after starting ART and some do not?

The majority of patients are able to tolerate ART well, even over years. Some may experience difficulties because of various factors such as the overall health condition of the patient, level of nutrition, other medication the patient is on, drug overdose or drug interactions and physical exhaustion.

Why do some people die after they start taking the drugs and some do not?

Some people go to the CTC clinic very late during the course of the disease. They may have a very high viral load, low CD4 count and very bad health condition, i.e. they are very weak, in poor nutritional state and have very serious opportunistic infections. Such patients do not respond very well to further treatment and most, unfortunately, die. In this respect it is strongly recommended that everybody goes for HIV testing to know their status. This allows starting treatment in time when it is highly effective.

Should a patient continue to take ARVs although he/she cannot take any food?

All efforts should be made to ensure that the patient continues to take ARVs even though he/she cannot take any food. However, food uptake should be encouraged and the causes for not being able to eat should be addressed. Weakness and poor nutrition affects the health of the patient. In such cases the patient should be taken to the doctor at the Care and Treatment centre (CTC) immediately, where he/she might have to get medication.

What things need to be considered when someone is using ARVs?

The most common things to consider when taking ARVs are:

- As with other medications, interaction with other drugs should be avoided.
- Do not take any other drugs that were not prescribed without talking to the doctor.
- Do not take more or fewer drugs than those prescribed by the doctor.
- Alcohol should be used moderately or rarely, if at all.
- Treatment should not be stopped without consulting a doctor.
- The type of drugs used should not be changed unless prescribed by the doctor at the CTC clinic.
- It is important for PLHIV on ARTs to protect themselves and their sexual partners from new infections with HIV and/or other STIs (HIV-infected people may be infected again with other strains of the virus, making the HIV infection more severe).

Where can one get ART?

The Government, through the Ministry of Health and Social Welfare, has selected and Approved more than 200 Care and Treatment Centers - both private and public – country wide to offer services to the public. The centres are located in referral

hospitals, regional hospitals, districts, and selected health centers and private hospitals both in urban and rural centers.

What measures are taken to ensure that ARV drugs are available in peri-urban and rural areas?

The national Care and Treatment Unit, under the Ministry of Health and Social Welfare, was established to coordinate and manage a nationwide programme. It includes the procurement of ARVs; their distribution to the various hospitals and CTCs, both in urban and rural areas; and training and recruitment of staff to manage the centers. Various partners, local and international, are also working closely with the government to support this programme.

How can disabled people access ART?

Like other patients, people with disabilities are encouraged to visit the nearest hospital or CTCs to get antiretroviral therapy. Close relatives of people with disabilities are encouraged to provide the necessary support to ensure regular attendance to the hospital or CTC.

What is the plan for children of PLHIV on their access to ART?

It should be remembered that only a minority of the children of PLHIV are infected with

HIV. In Tanzania if a child of a PLHIV is tested positive and medically diagnosed, the child will get access to ART at the clinic or CTC if needed. This is only the case for some of the infected children because treatment is only started if the immune system gets weaker.

This may not occur until many years after the HIV infection.

Are ARVs supplied to Tanzania of inferior quality?

All ARVs supplied to Tanzania undergo quality check and no inferior quality ARVs are distributed to the hospitals or CTC clinics. ARVs available in Tanzania are so called "generic drugs" as compared to "branded drugs". They are slightly cheaper than the branded ones (because the producing company, for example, does not invest in advertisements), but have the same quality standard as non-generic drugs.

What measures are being taken to reduce the price of ARV drugs?

ART drugs are available for free in government and non-government hospitals and health centers.

It is expected that through competition among different manufacturers, prices will fall, e.g., competition has been seen to reduce the price of a triple combination of antiretroviral from \$10,000 to \$300 in one year.

What role can the CMACs and community play in the Care, Treatment and Support Programme?

There is a common saying that “HIV is seen in the clinics, but lives in the community”.

This shows that the CMACs and community have an important role to play. The vast majority of people living with the virus do not know their status. Knowing your status is the only way to get effective treatment in time.

What CMACs can do:

- Advocate for people living in their district/municipality to test early and regularly for HIV. Early diagnosis of HIV infection increases the effectiveness of anti-retroviral therapy.
- Conduct mass campaigns to educate the public on the care and treatment programme.
- Advocate for more support (technical and financial) to the Care, Treatment and Support programme with local and international donors, organizations, and public and private companies and partners.
- Identify and then engage key partners and other community-based organizations to further the aims of the care and treatment projects.
- Advocate for adherence to treatment in collaboration with formal health services.
- The better the patient is informed and educated about treatment and the need for adherence, the better he/she will follow the instructions.
- Support Information, Education and Communication campaigns – also known as IEC campaigns - for the need to always have protected sexual relations, to remain in contact with the counselors, to be alert to drug interactions, to eat well, and to maintain a good personal hygiene.
- Collect information from the health sector on monitoring and evaluation of the Care,
- Treatment and Support programme and use the information when planning new activities.