

My Choice & My Life

英語版



ViiV Healthcare K.K.

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■ Introduction

This brochure is prepared for patients who are considering starting the treatment for HIV infection for the first time. We hope that this brochure will be helpful for understanding the relationship between the disease and therapy, the effect of treatment on patients' lives, and preparation for the initiation/switching of therapy.



Not knowing is

dangerous !!

Cases where patients make errors or lose benefits because of “not knowing” are increasing. Please don’t forget that people have made the following mistakes:

1 Stopping to visit the hospital

Even if you are not taking medications, regular checkups are always necessary. You must continue visiting the hospital. Physicians and hospitals can be changed. If you have any financial concern, please seek advice from the healthcare consultation office or nurses.

2 Taking medications on an on-and-off basis

As a consequence of such behavior, you may become non-responsive not only to the present medication but also to drugs with which you have not yet been treated. When there is any reason for being unable to take medications, you should let the physician, pharmacist or nurse know as soon as possible.

3 Being additionally infected with HIV from other people

Superinfection occurs due to a lack of prevention and the wrong belief that “I believed no condom was necessary for sexual intercourse between HIV-infected persons.” There are cases where treatment is unsuccessful because medicines were not effective for the virus. Make sure to always wear condoms during intercourse, and not take them off (including oral sex).

Frequently asked questions in the early

Q 1 I was informed to be “HIV-positive.” Do I have AIDS?

It means that you are infected with a virus called HIV (human immunodeficiency virus). Being infected with HIV and “AIDS,” which is a result of the progress of the disease, are not the same.

Q 2 I was informed that I have developed AIDS. Will I get better with treatment?

Many people can regain their health if they receive appropriate treatment for infections and HIV infection itself.

Q 3 I don't feel there is anything wrong with me. Should I go to the hospital?

It is important to have physical examinations and tests on a regular basis to check the immune condition as to not miss the time to start therapy even for those who are in excellent physical condition and are not requiring treatment immediately. Please remember to make periodic visits to the hospital.



stage – HIV infection and its treatment

Q 4 Which department should I consult?

We recommend meeting with physicians* specializing in HIV/AIDS treatment. Departments examining HIV infection vary according to hospitals. Call the hospital and check which department you should consult and when you should visit before going to the hospital.

Q 5 Can I continue working even if I start treatment?

Most patients keep on working as they have done while they continue treatment. Work is also important for maintaining a healthy life. If you have any worries about your health or if you feel stressed at work, please consult with your doctors, nurses, social workers, and counselors.

Q 6 Please tell me what I should confirm before I start treatment.

- 1 How much does treatment cost per month?
- 2 Is a welfare system available?
- 3 How and when should I take a procedure?
- 4 Is there any problem with combining treatment medicines with drugs that I'm currently taking?
- 5 Can I get pregnant even if I'm on drug therapy?

* Where can I find doctors specializing in HIV/AIDS treatment?

There are about 370 "hospitals specializing in AIDS treatment" in Japan. You should consult with doctors at any of these hospitals.

– AIDS Treatment Base Hospitals –

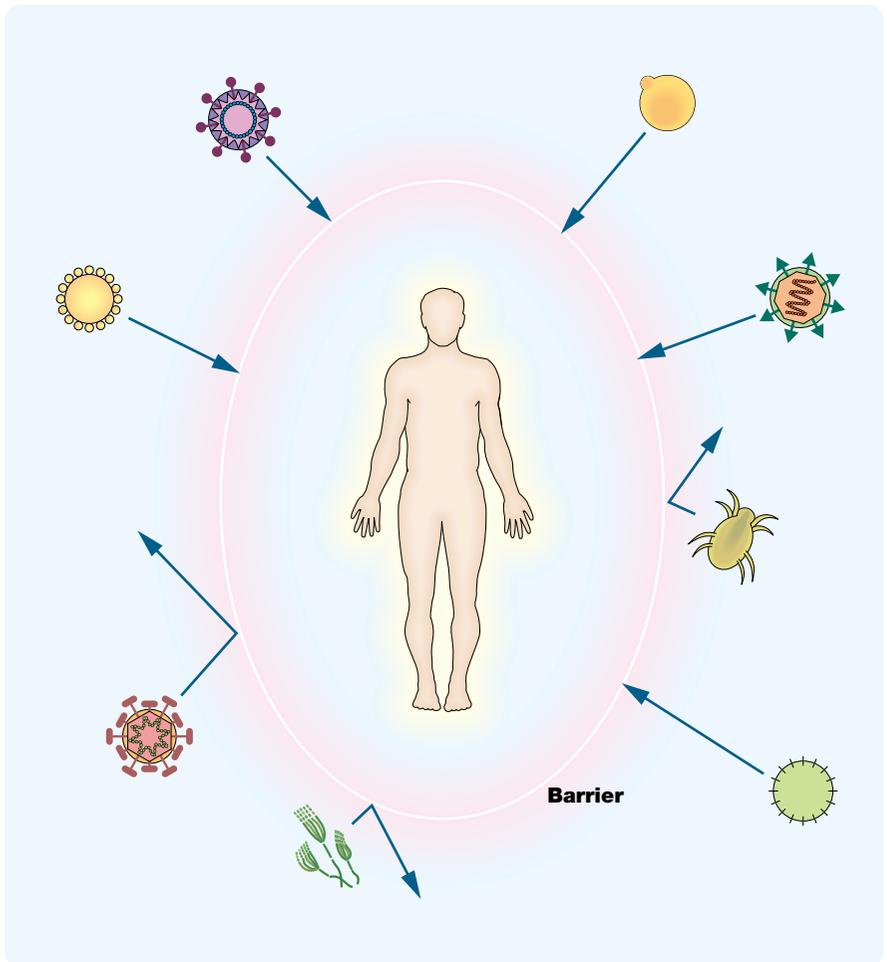
<http://hiv-hospital.jp/>



What is HIV infection?

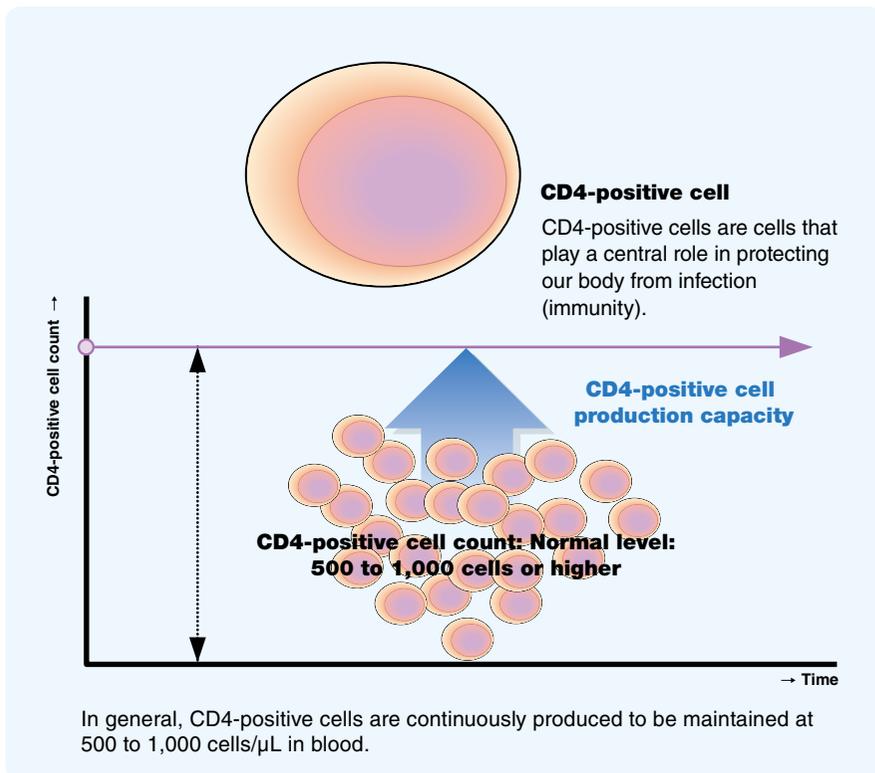
Q₁ What is immunity?

There are numerous bacteria, virus and fungi around us. However, because we have a barrier (resistance) called immunity, the majority of these pathogens cannot infect us. Even if we are infected, infection may naturally cure without manifesting any symptom.



Q2 What is a CD4-positive cell?

CD4-positive cells (also called CD4-positive lymphocyte) are cells that play a central role in protecting our body from infection (immunity). The cell counts can be determined by blood tests. If these CD4-positive cells are destroyed, the immune activity decreases resulting in a state of easy opportunistic infection*.

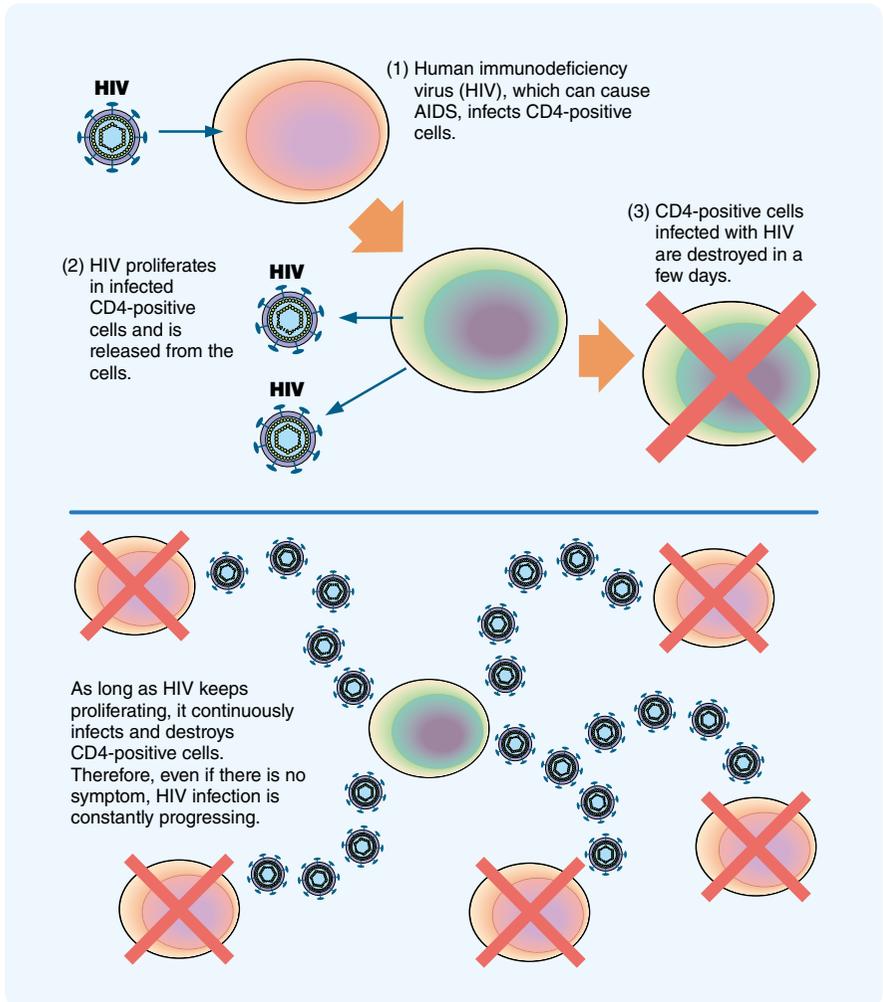


* Opportunistic infection

Opportunistic infection occurs when body resistance or the immune system is weakened so that pathogens, which usually do not cause infection or disease, induce infection.

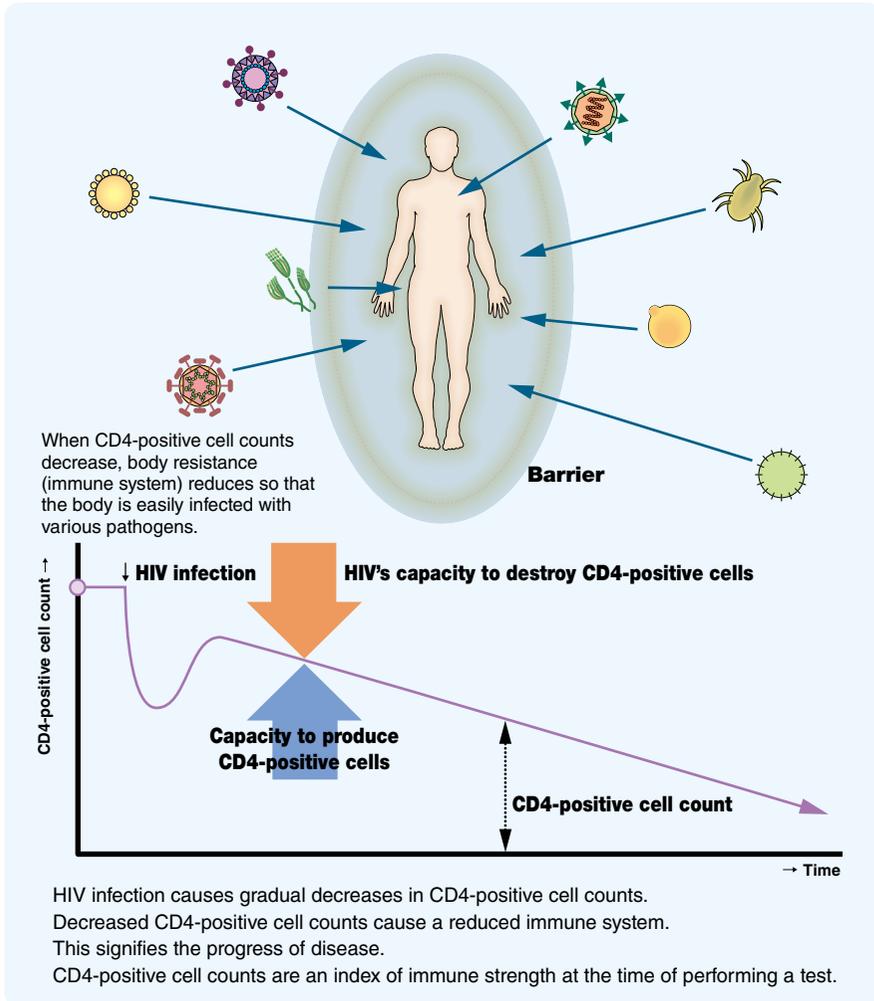
Q 3 How does HIV infect our body?

Human immunodeficiency virus (HIV), which can cause AIDS, infects CD4-positive cells and proliferates. CD4-positive cells infected with HIV are destroyed in a few days.



Q 4 What happens when CD4-positive cell counts decrease?

If HIV levels continue to elevate, CD4-positive cell counts gradually decrease. When CD4-positive cell counts decrease, body resistance (immune system) reduces so that various diseases can easily occur. Decreased CD4-positive cell counts mean a weakened body resistance (immune system); this also signifies the “progress of disease.”

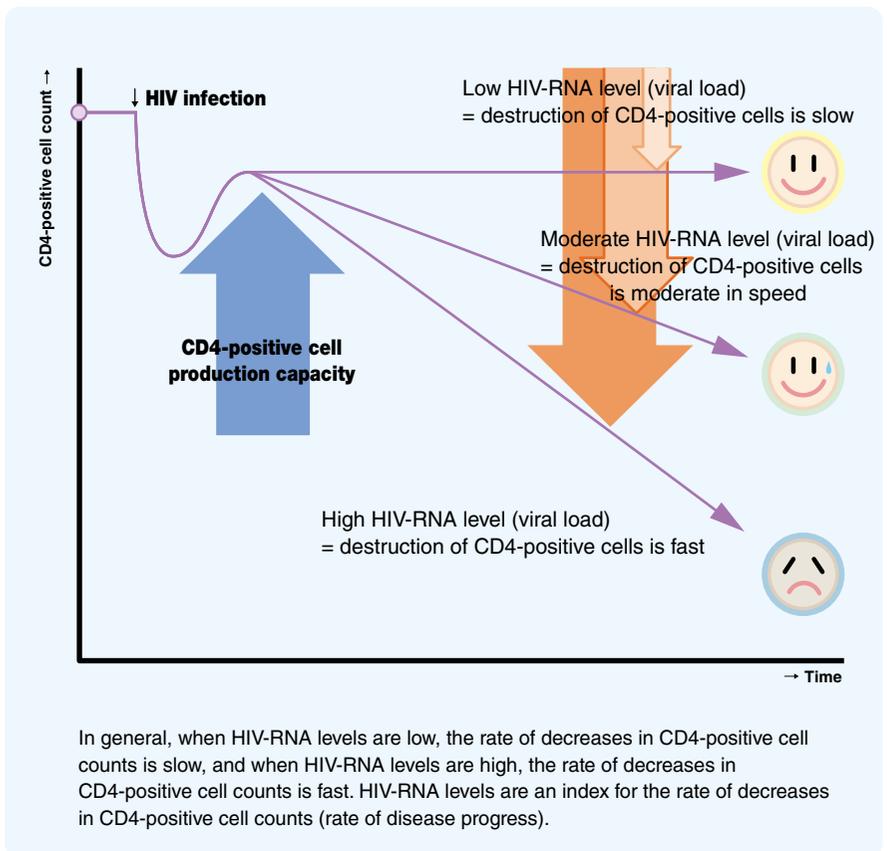


Q5 What is a viral load?

Viral load is the amount of HIV (HIV-RNA level) in the blood.

Disease progresses more rapidly in patients with a high viral load than those with a low viral load.

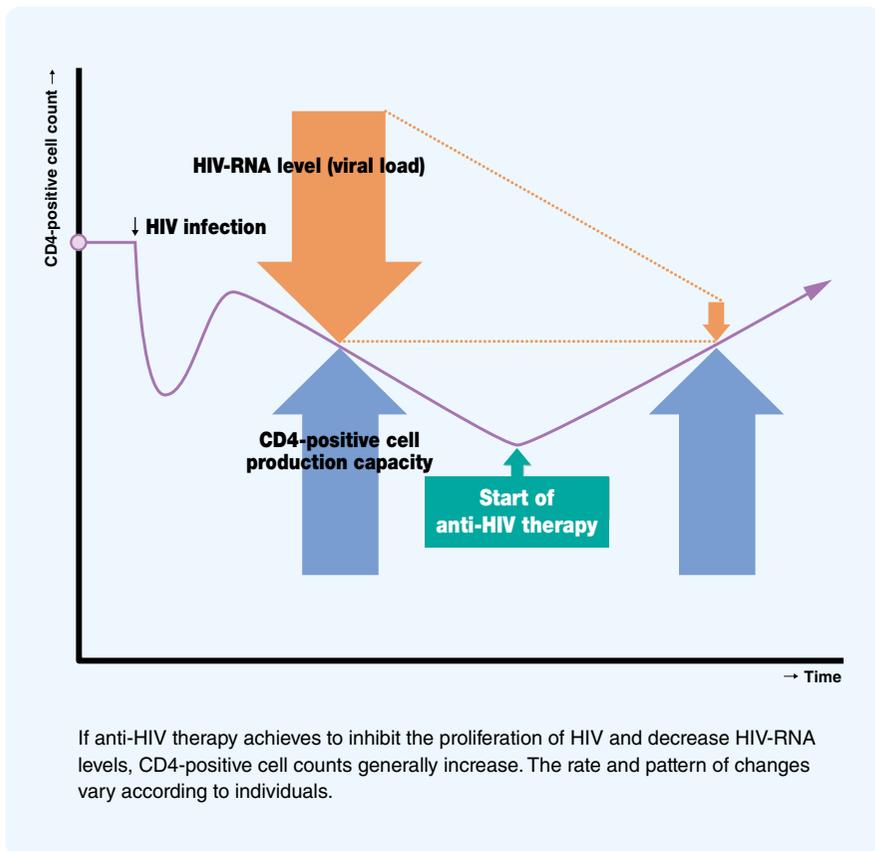
However, since the viral load and the speed of disease progression vary depending on the person, make sure to receive thorough explanation from your doctor.



Q 6 What is “anti-HIV therapy?”

Anti-HIV therapy is a treatment to reduce viral loads in patients with the use of anti-HIV drugs that inhibit the proliferation of human immunodeficiency virus (HIV)[also called ART (antiretroviral therapy)]. The effect of the treatment is identified based on blood test results such as CD4-positive cell counts and viral loads.

We advise you to record the results of every test.



If anti-HIV therapy achieves to inhibit the proliferation of HIV and decrease HIV-RNA levels, CD4-positive cell counts generally increase. The rate and pattern of changes vary according to individuals.

What treatments are available?

Q 1 What factors should I consider for treatment?

When to start treatment

Everybody who is known to be infected with HIV is encouraged to start treatment. It is known that if the treatment keeps the virus at a low level, it will not only allow you to maintain good health but also to reduce the risk of your sex partner's infection with HIV. However, if you have any comorbidity, the condition should be treated first. Moreover, since "resistant viruses," which do not respond to drugs, may appear if you forget to take the drugs, an environment that ensures continuous drug compliance needs to be established before the treatment is started.

Moreover, various tests, evaluations, and procedures are necessary before the start of treatment if you are to receive subsidy for medical costs.

Furthermore, you may need to adjust your schedule, for example, by avoiding starting treatment when you are busy with work because side effects are likely to occur during the period of 2 - 4 weeks after the start of administration.

Thus, various preparations are necessary before the treatment is started.

Therefore, it is important to consult with your doctor to carefully determine the best timing for you to start treatment.

◆ What should I do if I'm pregnant or giving birth?

When you find out that you are infected with HIV through pregnancy, generally speaking, to protect the mother's health and prevent mother-to-child transmission, you should receive anti-HIV therapy as early as possible, including the first trimester of pregnancy, if HIV infection has been detected. The selected drugs will be slightly different from the generally recommended drugs, so it is essential to consult HIV specialists.



With what combination of drugs should treatment be started?

◆ **Select drugs that show potent and definitive therapeutic effects.**

Every year, the “Anti-HIV Therapy Guideline” (<http://www.haart-support.jp/guideline.htm>), and the “Guide to Treatment of HIV Infection” (<http://www.hivjp.org/>) etc. are issued and the recommended combination of drugs slightly change. However, the basic policy to “concomitantly use multiple drugs out of about 20 drugs” has not changed. At present, with some drugs, you are able to select treatment using a combination of two drugs.

Currently, most of drugs are combination drugs. Dosage of those combination drugs are mainly 1 to 2 tablets once a day.

When selecting a drug, consider following conditions based on the individual situation.

- **Select drugs that do not require frequent daily dosing.**

All the doses of the combinations are 1 - 2 times a day

- **Select drugs that are most suitable for your work, eating and sleeping patterns.**

There are drugs that need to be taken after eating, drugs that are better taken on an empty stomach, and drugs that can be taken irrespective of meals.

- **Select drugs with few adverse reactions.**

- **Consider the interactions with the drugs you are currently taking.**

The combination that is likely to bring about the best results will be selected depending on the individual situations while taking the above conditions into consideration.

Will my therapeutic drugs be changed? If so, when will this happen?

- ◆ When treatment is no longer effective.
- ◆ When daily rhythm or schedule, which affects your living or dosing schedule, changes.
- ◆ When adverse reactions are severe and affect daily activities.
- ◆ When new treatment drugs, which can be more easily taken or are more effective, are released.
- ◆ When pregnancy or delivery is planned, or after giving birth.

What will the drugs be changed to?

- ◆ Consideration will be given to avoiding the situation where drugs cannot be taken due to the same reason as that for the previous treatment.
- ◆ The drugs will be switched to a combination that is likely to be most effective based on the results of drug resistance tests (a test to confirm whether the effectiveness of the drug is maintained against HIV (refer to page 15)).

* It is also important to review drugs that you have taken (their duration and effect).
Make sure to let your physician know about them.

Reasons for not taking drugs (being unable to take drugs) - the U.S.

Forgot	36%	Forgot	66%
Busy	27%	Left drugs at home	57%
Overslept	23%	Busy	53%
Left drugs at home	18%	Changes in daily rhythm	51%
Adverse reactions	13%	Overslept	40%
(Spire B. et al.: Social Science & Medicine 54, 1481-1496, 2002)		Problem with dosing timing	40%
		Poor physical condition	28%
		Adverse reactions	24%
		Depressed	18%
		Too many drugs to take	14%
		Didn't want other people to recognize that I'm taking drugs	14%
		Drug toxicity or adverse events	12%
		(Chesney MA et al.: AIDS CARE 12 (3), 255-266, 2000)	

When you have any worries, please consult with your physician, pharmacist or nurse.

Q 2 I intend to start treatment but am worried about adverse reactions and forgetting to take the medicines.

Whether or not adverse reactions occur and their severity, vary according to individuals. You should ask your physician or pharmacist beforehand about an approach to handle adverse reactions as to when and what symptoms may appear and what you should do when they occur.

For some medicines, the symptoms may abate with time, or their effect on your life can be reduced by shifting dosing time.

In order to prevent forgetting to take medicines, you should check your daily routine with hospitals (or medical institutions) staff to review a time when you can easily take (or forget to take) medicines and what approaches are available to prevent forgetting to take them with the physician, pharmacist or nurses before starting treatment. It may be useful to ask about approaches taken by other patients.

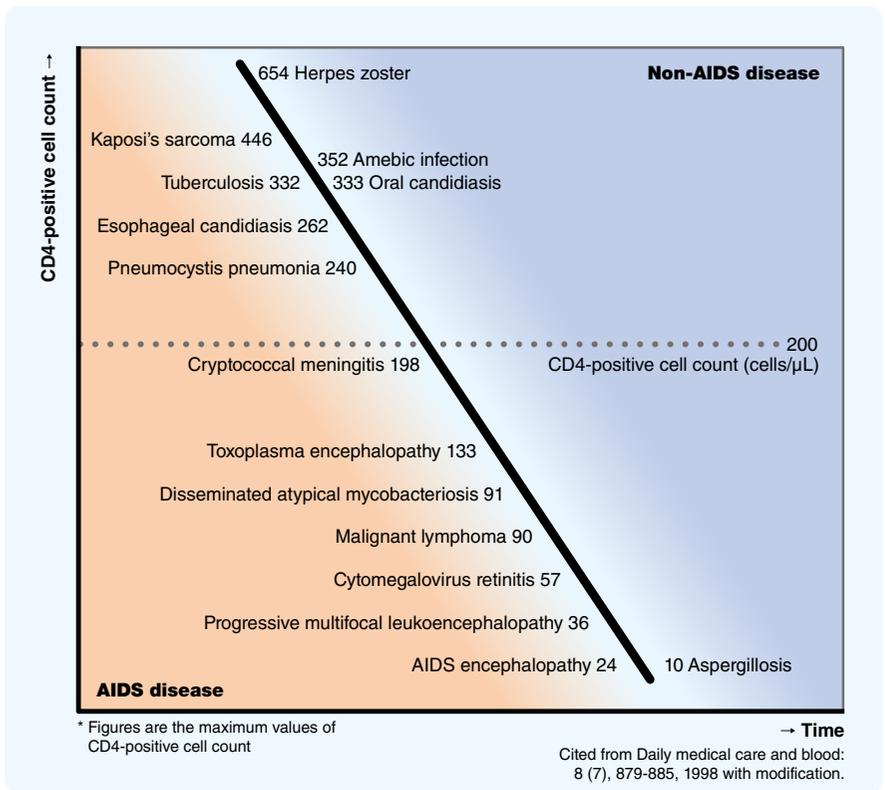
Many patients actually have these worries and questions. Treatment does not last long if you start it without being convinced or are not ready to start. Therapy should be started after you and your physician agree that “you can manage treatment with this method.”

You don’t have to initiate treatment immediately based on the results of only one test. If you need to think a little longer about starting therapy, you should ask the physician about “alternatives,” “what is the reason why you recommend me this treatment?” or “can I make a decision after I think about it for a little while?”

- **Even if treatment is not started immediately, you must be aware of your physical condition based on periodic blood tests. Don’t forget to go to the hospital.**
- **Information on treatment is rapidly updated. Data that you learned at the first consultation and those available at the time of actually considering therapy may vary. You should obtain information on treatment from the physician or pharmacist on a regular basis. If you tell them, “please let me know new topics when they come out,” you will not miss any information. It is also better that you frequently let staff know about yourself such as changes in job or lifestyle.**
- **Even if CD4-positive cell counts, representing the immune condition are high, you may have a disease associated with HIV infection (see page 13). If you feel any “abnormality,” consult with the physician as soon as possible.**

Q 3 At what count of CD4-positive cells do opportunistic infections occur?

In general, it has been reported that when CD4-positive cell counts reach 200 or less, various diseases and physical problems easily occur. Medicines may be used for their prevention. Even if counts are 200 or more, you may develop various diseases. Therefore, even if your physical condition is good and have not yet started anti-HIV therapy, make sure to have an examination to check your physical condition on a regular basis.



Q 4 Once I start treatment, do I have to continue for the rest of my life?

At the moment, you should remember that treatment needs to be continued throughout your life. However, it does not mean that you will take the same drug forever. As stated above, there are cases when drugs will be changed such as when adverse reactions occur, when the drugs become less effective or when drugs that are easier to take are approved. Currently, there are many patterns of drug combinations, and therefore drug switches during treatment are not unusual. Therapeutic drugs are progressing year by year, and therefore they will have less adverse reactions and become easier to take.

- **When adverse reactions associated with treatment are severe**
- **When anti-HIV drugs become ineffective for viruses (drug resistance) and are switched to a new therapy**
- **When treatment is replaced with drugs that can be easily taken or continued.**

When adverse reactions are severe, you have difficulty with continuing treatment in relation to work or daily life, or you want to give up treatment, first consult with your physician, pharmacist or nurse. Don't discontinue treatment suddenly or change the dosage of drugs on your judgment only.

Please do not take the following actions on your judgement only, first consult with your physician or pharmacist:

- **To stop taking drugs because your physical condition improved.**
- **To stop attending the hospital because your physical condition improved.**
- **To take larger doses of drugs because your physical condition is poor.**
- **To take double doses of drugs because you forgot to take the previous dose.**



Q5 What types of tests do I need?

Before starting anti-HIV therapy and also after its initiation, blood tests will be performed on a regular basis. In addition to general blood tests, viral loads and CD4-positive cell counts are measured in the blood test. Please use the table.

Table/ Necessary tests

Test name		What is examined?	Note
CD4-positive cell counts		CD4 and CD8 counts are examined.	They are used as ● indexes for learning your current immune condition; ● criteria for starting or changing treatment; ● criteria for the prevention or treatment of opportunistic infection; and ● criteria for certification as physically handicapped persons*1.
Amount of HIV-RNA*2 (Amount of virus)		The test shows the amount of virus in your blood.	They are used as ● indexes for changes (progress of the disease) in your subsequent immune condition; ● criteria for starting or changing treatment; and ● criteria for certification as physically handicapped persons.
Blood count Ex.: Red blood cells, white blood cells, platelets, etc.		The test reveals whether you have anemia and/or infection and blood does not easily coagulate.	● Results fluctuate according to your physical condition or drugs you are taking. ● Results fluctuate according to your physical condition or food you ate. ● Results are used as indexes for identifying adverse reactions associated with drugs.
Biochemistry Ex.: blood sugar, cholesterol, neutral fat, AST (GOT), ALT (GPT), g-GTP, creatinine, etc.		The test shows the general conditions of the liver, kidneys, pancreas and other organs.	
Other infection tests Ex.: Hepatitis A, hepatitis B, hepatitis C, sexually transmitted diseases (STD) such as syphilis, toxoplasma, etc.		The test can tell you if you have a disease that is transmitted by the same route as HIV.	● HIV treatment may affect the test results. The test is performed at initial examination and subsequently when needed.
Resistance test/ Blood drug concentration measurement	Resistance test (genotype and phenotype tests)	The test helps to identify which drugs are expected to be effective.	● The test data are important for switching treatment. You should inform the physician when you desire to have the test.
	Blood drug concentration measurement	The test confirms whether drug concentration is sufficient for exerting a therapeutic effect are maintained or too high in the blood.	● The test is performed when the physician finds it necessary.

Reference: European AIDS Clinical Society GUIDELINES 8.0 PART1 p1-2

* CD4-positive cell counts and viral loads vary according to changes in your physical condition such as having a cold. It is important to sequentially measure them several times.

* Reference values (levels in normal ranges) vary according to hospitals. You should confirm them. In addition to these, urinalysis, X-ray examination or other tests are added according to symptoms.

***1 Certification as physically handicapped persons**

Certification for physically handicapped persons has been granted for HIV infection as “immune dysfunction” since April 1998 so that the medical cost subsidy system can be used. Criteria for certification as physically handicapped persons and specific application procedures vary according to the area where you reside. Please ask your physician, nurse or healthcare counselor (MSW/social worker).

***2 Amount of HIV-RNA**

Blood HIV-RNA level is also called a viral load.

Q 6 How much does treatment cost?

The current treatment of HIV infection is a combination of multiple anti-HIV drugs and costs approximately over 100,000 to 200,000 yen per month. Patients who have treatment for other diseases need to pay additional costs. Since the healthcare insurance that you have can be used, you pay 30% of the medical expenses at the hospital.

In order to reduce this self-pay burden, a system for high medical costs exceeding a certain standard price or healthcare support for independence of handicapped persons on condition of obtaining a physical disability certificate can be used. For further details please ask healthcare counselors (MSW/social worker) or nurses.

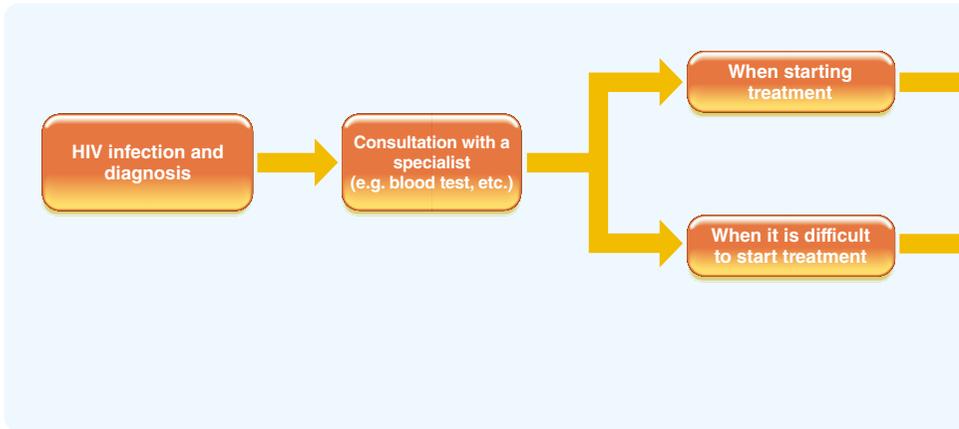
- HIV/AIDS information net for Kanto-Koshinetsu region •

– Guide for systems –

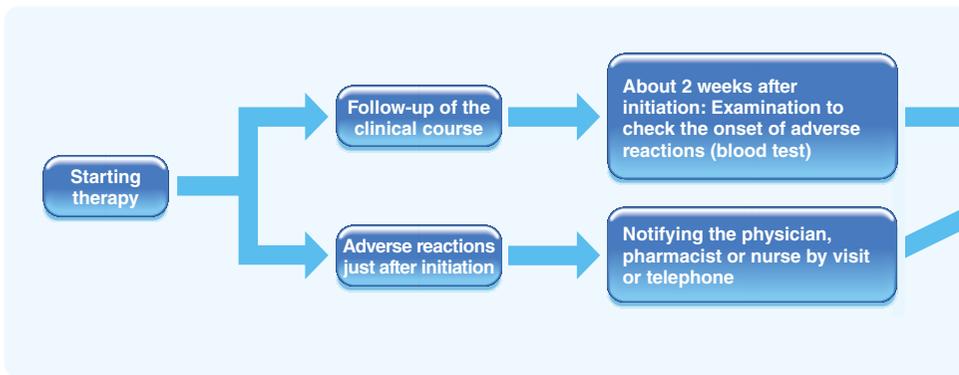
<http://kkse-net.jp/tebiki.html>

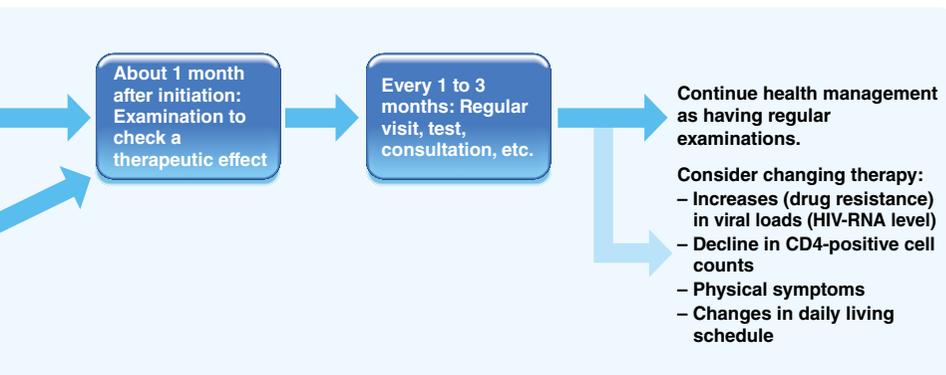
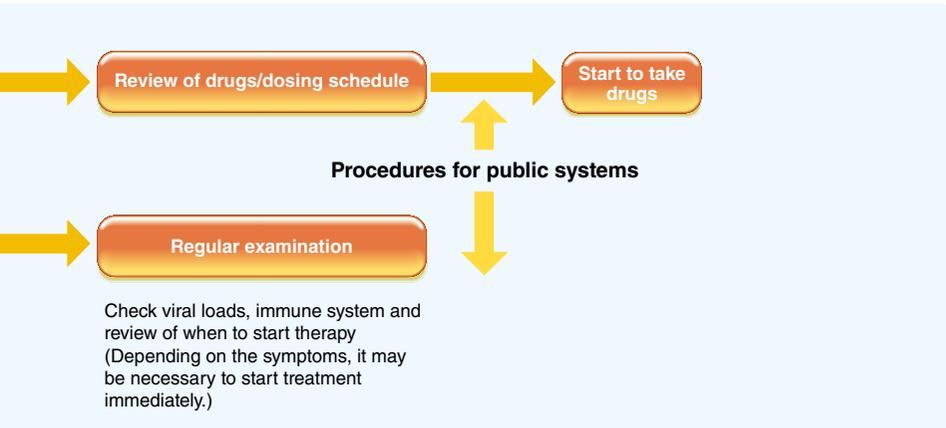


◆ Until anti-HIV therapy is started (example)



◆ After starting anti-HIV therapy (example)





Keeping therapeutic effects

Keep stocks of treatment drugs

When you are unable to visit the hospital on the date of appointment, notify the hospital to change the appointment and visit before you use all of the drugs. When a business trip or travel is planned, secure an extra stock of medicines in advance. If you forget drugs or lose drugs during your trip, go to a nearby specialized hospital. You should also ask your physician or nurse about the nighttime system of the hospital pharmacy.

Precautions to be observed

Predefined matters such as time and meals should be respected. For instance, there are medications that should be taken during meals or on an empty stomach or that do not concern meals.

Use an alarm or timer

Some patients use the alarm or vibrator function on their cellphones; others use the reminder function and support apps, available on websites. The key to avoid forgetting to take drugs is to take them at the time you had predetermined. Another approach is to specify dosing timing according to your work or school schedule.

Keep drugs in a place where you are likely to be present at the dosing time

Some patients put drugs which are taken in the morning or at night on the dinner table, near the washing stand, in the kitchen, near alarm clock or near pots. If you often go out for business, have an irregular traveling or daily pattern, contrive an approach to keeping some portions of medications at work or carry them with things that you always carry around.

Prepare against disasters

When you have taken the drugs for more than six months and your status has become stable, we recommend you to secure extra drugs for more than a month.

In times of big disasters, you may be prescribed at temporary medical institutions. Thus, it is better you remember what you take and how you take them accurately. Furthermore, if you make sure to carry a memo of your drugs with your identification card or your patient registration card, you can expect to receive appropriate treatment even when you are unable to indicate your intention.

Other questions

Q 1 I was informed that the viral load was less than the detection limit in blood test results. What is this condition?

It means that the amount of virus (HIV-RNA level) in the blood is so small that it cannot be determined with the current test method. The purpose of treatment is to continue to hold the viral load (HIV-RNA level) in the blood to below the detection limit, so please continue to take drugs and make regular hospital visits.

Q 2 I decided not to start treatment now as a result of consultation with my doctor. Is it necessary to test viral loads and CD4-positive cell counts in the future?

Yes. Even if you have not yet started drug therapy, it is important to be aware of your physical condition on a regular basis. You should determine how often you visit the hospital and have tests upon discussion with the physician. You should keep reviewing when to start therapy with the physician.

Q 3 Is it okay to take anti-HIV drugs with health foods or supplements?

It has been identified that there are not only medicines but also some health foods that should not be combined with anti-HIV drugs. You should consult with your primary doctor or pharmacist about not only medicines prescribed at other hospitals and over-the-counter drugs purchased at pharmacies but also health foods and supplements that you are taking.

Q 4 I found on the Internet that new medications have been released. I believe that a better treatment may be obtained if switching to the new drugs.

Medications are definitely improved in various points such as their sizes, dose frequency and treatment restrictions and adverse reactions recently. It is good to consult with your physician about new medications and consider them as future alternatives.

Q5 Are there any precautions to be exercised for having sexual intercourse in the future?

Perform prevention using barriers such as condoms so that your sexual organs, anus and mouth do not come into direct contact with the partner's membranes or body fluid in order to avoid contracting another STD. The prevention of infection is necessary even when the partner has HIV infection.

Effect on the partner **Risk of HIV infection**

A recent report* shows that, if the viral loads are kept at levels below the detection limit for 6 months or more, with treatment, you no longer pass HIV on your sexual partner as well. Continuation of appropriate treatment is important for your partner as well. However, to prevent other sexually transmitted diseases also, make sure to practice safer sex by using condoms and other means.

* Alison J Rodger et al. JAMA 2016; 316:171-181
Alison J Rodger et al. Lancet 2019; 393:2428-2438

Effect on your physical condition

- (1) Being affected with another infection → Adverse effect on immune function and increases in viral loads
- (2) Being infected with another pathogen in addition to HIV → Risk of treatment failure

Note 1: Consult with the physician or nurse on measures for risks of transmitting the disease to the partner due to breakage or coming off of a condom.

Note 2: It is important to avoid pregnancy during an undesired period. Ask the physician or staff about more definitive contraception and appropriate timing for pregnancy and delivery.

Q6 Is it difficult for me to have a baby in the future?

Pregnancy can be planned while continuing HIV treatment. What is important, however, is “planned pregnancy,” to fully understand the treatment status, and to prevent the transmission of infection to your partner as well as from a mother to child, and make preparations.

For women with HIV infection, attention must be paid to drugs which should be avoided during pregnancy, and to adverse reactions.

For men with HIV infection, natural pregnancy* is considered possible if they meet the conditions described in the guidelines, such as maintaining the blood viral load below detection level for a set period or longer¹⁾.

On the other hand, there also is the option of conducting infertility treatment in case repeated natural intercourses do not result in pregnancy²⁾.

When you wish to become pregnant or have a baby in the near or distant future, consult with your physician or staff as early as possible.

- **For men who are HIV-positive: If artificial insemination or in vitro fertilization is to be performed, a method of removing HIV in semen is available^{1) 2)}.**
- **For women who are HIV-positive: Prevention of transmission between partners and from a mother to child is necessary.**

Please consult a doctor of staff regarding concrete methods, each of their risks, medical institutions that perform artificial insemination and/or in vitro fertilization, including cases where both the husband and the wife are HIV-positive. To ensure an even safer planned pregnancy, it is important that you perform sound contraception on a routine basis.

※ Refers to becoming pregnant by normal sexual intercourse without receiving medical treatment

Citations:

1) NICE Guidelines:

<https://www.nice.org.uk/guidance/cg156/ifp/chapter/HIV-hepatitis-B-and-hepatitis-C>
(browsed October 2020)

2) Naoaki Kuji et al., A study on reproductive medicine of people who are HIV-positive. 2017; FY2015-2017, Health and Labour Administrative Promotion Survey Project Grant (Anti-AIDS research project)

[Reference] Consultation when men are HIV-positive and women are HIV-negative

- **Department of Hematology, Ogikubo Hospital** •

<http://www.ogikubo-hospital.or.jp/department/blood.html>



**Q7 I'm a pregnant woman infected with HIV.
How should I have treatment? How can I avoid
transmitting HIV to the baby to be born?**

There are several approaches for avoiding transmission of HIV to babies. First, the following points will be reviewed with the physician in consideration of viral loads, CD4-positive cell counts, whether or not anti-HIV therapy has been started, and which pregnancy period you are in: (1) reducing your viral loads as low as possible, (2) selection of drugs for treatment during pregnancy and cesarean section, and (3) administration of a prophylactic to the baby. Breast-feeding should be avoided because there is a risk of transmission of infection and so powdered milk is given.



• **Research Group for Therapy of HIV Infection** •

– Guide to Treatment of HIV Infection –

There are sections concerning treatment in pregnant women and the prevention of mother-to-child transmission.

<http://www.hivjp.org/>



• **API-Net AIDS Prevention Information Network** •

– Manual on Measures for Preventing Mother-to-Child Transmission of HIV –

<http://api-net.jfap.or.jp/library/guideLine/boshi/index.html>



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An illustration of three people walking from left to right. On the left, a woman with long dark hair, wearing a purple long-sleeved shirt and white pants, is looking down at a smartphone. In the center, a man with short dark hair and glasses, wearing a blue long-sleeved shirt, is looking forward. On the right, a man with short light-colored hair, wearing a light-colored shirt, is walking. Above them is a large, multi-colored rainbow arching across the sky. In the background, there are silhouettes of city buildings. The overall color palette is warm, with yellows, oranges, and browns.

To access “Patient Voice,” which are videos showing comments of people who are HIV-positive, please view “LiVLife,” a website for people who are HIV-positive and the general public, at:



<https://livlife.com/jp-jp/>

