

FREQUENTLY ASKED QUESTIONS TO EXPERTS OF AIDS HELP LINE OF ISTITUTO SUPERIORE DI SANITÀ

INFORMATION ABOUT THE TEST

- Q. What examinations must be done to detect an HIV infection?
R. The most common tests are Elisa and Western Blot. The first is used as a preliminary test, the second one as a confirmatory test.
- Q. Is it possible to undergo examinations and checkups anonymously?
R. Yes, in most of Health facilities anonymity is granted. Anyhow, the HIV test is strictly confidential. Moreover, according to the Law 135 of 08/06/90 –art 5) no one can be HIV tested without an informed consent, and the results can't be disclosed to other people than the person concerned or his/her legal tutor.
- Q. Is HIV test always free within Public Health Facilities?
R. Yes, the HIV test is free according to the Ministerial Decree of February 1991 that lists diseases that are free of charge within public health assets. Moreover, HIV test is anonymous according to Law 135 of 1990. The Ministry of Health will launch in 2008 and in cooperation with Regions and self-governing Provinces, a nationwide monitoring system of the diagnosis of new HIV infections. The monitoring system will also assess the implementation of Regulations aimed at granting anonymity and free HIV testing within ASL. Foreigners can have the test on the same conditions than Italians, even if lacking the Permit to stay in Italy.
- Q. When is it suitable to do the HIV test?
R. When s.o. has run a real risk (unprotected intercourses, sharing syringes with drugs addicted people, exchanging or transfusion of infected blood and perinatal HIV transmission). N. B. Hiv testing is better 6 months after the last risk behaviour, time used by the body to produce the specific anti-bodies against HIV.
- Q. When is it useless to repeat the test?
R. When the test done 6 months after the risk behaviour is negative.
- Q. Is a positive result always a signal of the HIV infection?
R. Yes, if it has been confirmed with Western Blot.

WAYS OF HIV TRANSMISSION

- Q. How is HIV transmitted?
R. HIV is transmitted
- By sexual intercourses (vaginal and anal penetration, oral-genital intercourses) that are unprotected or not properly protected with a condom
 - By the blood, if there is a sharing of infected syringes , if the infected blood is put in contact with bleeding wounds and when the infected blood comes into contact with mucous membranes, even uninjured, during sexual intercourses
 - By infected mother-foetus channel.

- Q. Which body fluids do transmit the virus?
 R. The body fluids that can transmit HIV are : sperm, pre-coition liquid, vaginal secretions, blood and mother's milk
- Q. Why are anal intercourses considered more risky?
 R. They are more risky because the anal mucous membrane is very fragile and this kind of intercourse can cause slight wounds that increase the hazard of being infected.
- Q. Why are injection-drug users considered persons at higher risk for HIV infection?
 R. Because they generally exchange non sterile syringes, drip with infected blood
- Q. Do unprotected intercourses with different partners increase the risk of being infected with HIV?
 R. Yes, if condoms are not used properly during the sexual activities
- Q. Can sex workers transmit the HIV infection?
 R. Yes, if they are infected and have unprotected intercourses. There are no people at high risk, but high risk behaviours.
 The HIV infection is transmitted whenever sexual intercourses are not properly protected, regardless of people's gender, age, religion, race and socio-economic status. If a client is HIV positive, he may infect the sex worker, if no condom is used properly.
- Q. Can people with transfusion-associated HIV infection transmit it during intercourse?
 R. Yes, if they don't use properly condoms.
- Q. What kind of risks do HIV infected people and their partners run if they keep on having unprotected sex?
 R. Behaving this way, they can infect other people, re-infect themselves and run the risk of getting exposed to other infectious diseases.
- Q. How can children get infected with HIV?
 R. They can be infected by an HIV positive mother during pregnancy, delivery and breastfeeding. That is why Hiv infected mothers have antiretroviral therapy, a caesarean delivery, and must avoid breastfeeding. Following correctly this procedure reduces considerably the risk for transmitting HIV to the infant.
- Q. Does an HIV positive person show signs/symptoms?
 R. No, because the infection can be asymptomatic for a long period.

PSYCHOLOGICAL AND SOCIAL ASPECTS

- Q. Can the HIV infection be a factor of discrimination?
 R. No, given that the Law 135-art 5 of 8/6/1990 was designed to protect HIV positive persons against any kind of discrimination (medical, social, at work...)
- Q. Can anyone with HIV or with AIDS be dismissed for these reasons?
 R. Not at all, according to the Law 135 - art5- of 8/6/1990
- Q. Can a medical care provider refuse to assist an HIV positive person or s.o. with AIDS?
 R. No, because HIV positive persons and patients with AIDS have the right to appropriate assistance and care as anybody else living in Italy.

PREVENTION

- Q. How can the HIV infection through sexual intercourse be avoided?
R. Using correctly the condom.
- Q. Does the condom prevent the risk for acquiring HIV infection?
R. Yes, when it's used from the beginning and during the whole intercourse, and if it isn't broken. For a proper use, see instructions on the package.
- Q. Is the condom necessary even for a single intercourse?
R. Yes, because one can get infected even after one intercourse.
- Q. Is it possible to get infected through transfusion nowadays?
R. It occurs very rarely, blood donors are strictly screened since 1985.
- Q. Can people with risk behaviours donate blood?
R. No, they may be HIV positive and therefore infect others.

MISINFORMATION

- Q. Can HIV penetrate an undamaged skin?
R. No, because the skin is a shield, a barrier protecting our body.
- Q. Is it dangerous to share the same spaces with HIV positive or people with AIDS?
R. No, living and sharing the same spaces with them doesn't represent any risk.
- Q. Can HIV be transmitted through a "deep kiss"?
R. No, except when there are visible wounds and bleeding in the mouth.
- Q. Can anybody acquire HIV sharing glasses and plates with an infected person?
R. No, because the saliva doesn't transmit this kind of virus.
- Q. Can tears and sweat transmit HIV?
R. No. Tears, sweat, saliva, urine, faeces, vomit, mucous don't transmit HIV.
- Q. Can using razor and toothbrush from an HIV positive person bring to acquiring HIV?
R. No, given that the virus is transmitted when there is a direct contact with infected blood. In any way, it's good, for the common sense and hygiene, to use personal effects regardless of the knowledge of someone's clinical conditions.
- Q. Can the dentist's instruments transmit HIV?
R. No, because these instruments are high-temperature sterilized in a way that no virus can survive.
- Q. Can insects and domestic animals transmit HIV?
R. No, the transmission man-animal and vice versa is impossible. The only possible way is HIV infected man-to-man transmission.
- Q. Can an HIV positive child infect another child(sane)?
R. No, nobody has ever been HIV-infected through socialization.

- Q. What are the precautions to be adopted by the school staff when an HIV positive child is bleeding?
- R. Like in every situation of exposure to other people's blood, gloves have to be used for medications and to stop the bleeding.

INFORMATION ABOUT THE VIRUS AND SCIENTIFIC RESEARCH

- Q. What is the cause of the HIV infection?
- R. The infection is caused by a virus conventionally called (since 1986) Human Immunodeficiency Virus- HIV. Two main types that seem to have pathological and clinical similarities were discovered: HIV1 and HIV2.

- Q. How many HIV positive people are there in the world?
- R. According to estimations made on December 31th 2005, they are between 33 and 46 million (Report UNAIDS 2006)

- Q. How many people with AIDS are there in Italy?
- R. From 1982 to December 31th 2005 the Reparto di Epidemiologia del Dip MIPI of Istituto Superiore di Sanità reported 56.076 cases.

- Q. How many HIV positive people are there in Italy?
- R. They are estimated between 110.000 and 130.000 (Reparto di Epidemiologia del Dip MIPI of Istituto Superiore di Sanità)

- Q. What kind of medicines are currently used for the treatment of HIV positive and people with AIDS?
- R. Combined therapies (HAART: High Aggressive Antiretroviral Therapy) consisting of a mixture of different medicines that helps to improve the quality of life and prolong the life expectation.

- Q. How far has got research with its work?
- R. At the moment, scientific research is headed for the experimentation of new drugs and vaccines.

- Q. What is a vaccine?
- R. A vaccine is a product that stimulates and brings the immune system to react against a specific micro-organism. Vaccines were conceived to prevent infectious diseases. The administration of a vaccine creates a body immune response that determines the protection of the person that was vaccinated against one or more bacterial or viral diseases (in case of combined vaccines). Vaccines are made of live and whole bacteria or viruses that are then killed (made inactive) or of fragments of a specific micro-organism.
 These inactive vaccines stimulate the production of anti-bodies but don't cause the infection. The third type of vaccine is produced with live micro-organisms that were attenuated and are able to induce an asymptomatic kind of the disease and consequently the production of anti-bodies.
 The specificity of universal immunization programmes is based not only on the safeguard of the vaccinated person, but also on the safeguard of the whole population, by reducing the circulation of the agent that causes a determined disease.

- Q. What is a preventive vaccine?
- R. A vaccine that aims to prevent an infection or a disease in a healthy person.

Q. What is a therapeutic vaccine?

R. A vaccine administered to an infected or sick person. The objective is to induce or empower the specific immune reaction in order to control the evolution of the infection or the disease. A therapeutic vaccine is potentially perceived as a further weapon to control the disease evolution.

Q. What is a clinical trial ?

R. Clinical trials are made to check if new therapies (vaccines and medicines) can be administered to human beings, if they are harmful, if they present side effects, if they are effective for the fight and prevention of infections and to define the correct doses to administer. The experimentation of a new therapy follows three steps, conventionally called Phase 1, Phase 2 and Phase 3.

Usually, before new substances are experimented on human beings, they undergo long and numerous laboratory tests. Then, they are tested on laboratory animals (mouse, rat, rabbit, ape). This phase is called pre-clinical experimentation. If experiments on animals demonstrate that the substance is not toxic but effective, researchers evaluate the opportunity to launch the phase 1 of the clinical experimentation.

Q. What is the TAT protein-based vaccine?

R. It's a vaccine against HIV obtained from TAT protein that is necessary to the replication of the virus. TAT is considered a special protein for many reasons. First, TAT is a regulator, a motor protein i.e. non-structural. In other terms, the vaccine experimented by Istituto Superiore di Sanità presents a rationale, i.e. a scientific approach completely different from the one used to develop the other vaccines experimented in the world until now.

These vaccines were concentrated on the external proteins of the virus; the aim was to obtain an immune sterilization i.e. the production of anti-bodies able to stop the virus before it enters the cell.

The TAT vaccine, on the contrary, can't block the penetration of the virus in the cell, but it is able to stop its activity, and hence, its replication. The immune response against TAT protein is expected to make the infection fail to spread.

The preventive function of TAT vaccine derives exactly from its capability to stop the first phase of replication of the virus. When an infection occurs, the virus enters the cell and begins its proliferation mechanism, producing lots of copies that spread through the body.

If this phase is blocked, the virus will fail to reproduce itself. The pre-clinical experimentations on apes were carried out as follows: the virus entered the cell (proviral DNA traces were found) but couldn't replicate, which means that there was no evolution of the infection. Later on, studies showed the absence of the virus in the laboratory animals that were used.

It means that the vaccine succeeded to stop the infection in the animals' bodies so early that it couldn't start replicating.

In the second hypothesis, less effective than the previous, the virus may succeed to start its replication but be kept under control by a functioning immune system. In a such case, the viral replication remains very low and the disease is kept under control. Reliable data Reports by International studies agree on the critical role played by the first phase of replication of the virus in the evolution of the disease. In other words, the virus is more likely to lead quickly to the disease when there's been its replication at the beginning of the acute infection.

Q. Can this vaccine protect against the HIV infection?

R. It doesn't prevent the infection, but it may control the virus multiplication and, therefore, the progression and the transmission of the disease.

Q. Can TAT vaccine be preventive and therapeutic at the same time?

R. Yes. Given that it may be able to control the multiplication of the virus, it can be used as a preventive vaccine to stop the first series of replication of the virus and its diffusion into the

body. As a therapeutic vaccine, it may stop the progression of the disease in HIV positive people.

Q. Is TAT vaccine effective on human beings?

R. We can't really tell. We only know that experiments on apes have demonstrated its effectiveness.

Q. When will it be available on the market?

R. Additional years are needed for clinical experimentations to assess the safety and the effectiveness of the vaccine before its administration against HIV/AIDS. Before a vaccine is put on the market, its effectiveness has to be confirmed through Phase 3 of the clinical experimentation, which should take 7-10 years in this case.

Q. What are the results obtained with the experimentations of phase1?

R. This first phase of the experimentation on human beings had to verify the safety of the vaccine TAT, to ascertain the absence of any toxicity for human body. The vaccine was found safe and well tolerated by the patients. No toxic traces were found no meaningful unfavourable events noticed, except local irritations due to injections, and slight fevers, very common in immunizations.

The secondary objective of this phase was to assess the vaccine's immune generating capability. A specific immune response was noticed among both healthy and HIV positive persons. Concretely, 100% of vaccinated volunteers have developed specific anti-bodies, both on the preventive and therapeutic basis. The cellular response, i.e. the reaction of specific cells able to recognize theTAT protein was induced in 93% of healthy volunteers (preventive protocol) and in 83% of HIV positive volunteers(therapeutic protocol).

Q. What is the next step?

R. The clinical trial of TAT vaccine will continue with experimentations of Phase2 on Hiv negative volunteers at risk for acquiring HIV infection (preventive vaccination) and on HIV positive volunteers, under treatment or not(therapeutic vaccination).

Q. Q. How to get updated scientific information about HIV infection and AIDS?

R. R. Information can be obtained calling, free of charge and in anonymity, the AIDS HELP LINE(800 861061) of Istituto Superiore di Sanità.

Expert researchers answer questions from Monday to Friday, from 1:00 to 6:00pm.

Every year, the Help Line works from 10:00 am to 6:00 pm on December 1st, the World AIDS Day.