CONSEIL NATIONAL DU SIDA
25-27 RUE D'ASTORG
75008 PARIS
T. 33 [0]1 40 56 68 50
F. 33 [0]1 40 56 68 90
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REPORT AND OPINION

SCREENING, HEALTH CARE PROFESSIONNALS EN

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SCREENING IN THE HOSPITAL CONTEXT FOLLOWING ACCIDENTAL EXPOSURE TO BLOOD IN SITUATIONS WHERE THE PATIENT IS UNABLE TO RESPOND TO A PROPOSAL FOR HIV SCREENING

Adopted at the full session, after tabling by the "Medical Aspects" committee.

Committee chair : Jean-Albert Gastaut, Chairman of the national aids council

Committee members :

- Françoise Brun-Vézinet
- Claudine Herzlich
- Catherine Leport
- Alain Molla
- Jacques Pasquet

With the participation of :

- Jean-Marie Faucher
- Patrick Verspieren

Rapporteur : François Buton

In a letter dated August 24, 1999, Dominique Gillot, Secretary of State for Health and the Disabled, asked the National Aids Council to examine some of the issues raised by the "testing for the serological status of the source patient with respect to HIV". After beginning by restating that the authorities had issued new "recommendations for the implementation and monitoring of antiretroviral treatment following exposure to the risk of HIV infection" in 1998, the referral letter went on to stress that the "the source patient's serological status with respect to HIV" was an "important item of information to be taken into account in reaching decisions, both for the evaluation of the potential risk of infection, and for any treatment to be suggested". Thirdly, the letter drew the National Aids Council's attention to a specific type of "situation" in the hospital environment (public or private), described as one in which "the proposed tests may be incompatible with the condition of the person concerned (anaesthesia, coma, etc)".

1) ANALYTICAL DESCRIPTION OF THE SITUATION TO BE EXAMINED

The National Aids Council considers that the type of situation it has been asked to examine **combines three main parameters**:
– Firstly, an **accident occurs to a healthcare professional involving exposure to blood**,
– Secondly, the **patient's HIV status is unknown**, and the patient has not previously refused a screening test,
– Thirdly, the patient is in a **specific medical situation preventing any response** to a proposal for screening: he or she may be a **coma**, or suffering from **prolonged loss of consciousness**.

A) PROPHYLACTIC TREATMENT FOLLOWING ACCIDENTAL EXPOSURE TO BLOOD: SITUATIONS CHARACTERISED BY AN URGENT NEED FOR ACTION

The first parameter defining the healthcare professional's exposure to risk of HIV/AIDS infection, is **the urgent nature of the situation**: when an accident involving exposure to blood occurs to a healthcare professional, there is a risk of HIV/AIDS infection which must be dealt with as a matter of urgency.

The circular of April 9 1998, to which the letter of referral alludes, does in fact recommend antiretroviral treatment be administered to any such member of the care staff **as quickly as possible**, i.e. **in the first few hours after** the exposure to HIV infection[1].

It bases this on the findings of the most recent work on early diagnosis of HIV infection[2], and that of the group of experts led by Professor Jean Dormont on the strategies for use of antiretrovirals in treating HIV infection (in October 1997), findings confirmed by the recommendations of the expert group on the medical treatment of individuals suffering from HIV infection, led by Professor Jean-François Delfraissy (1999).

According to the above work, prophylaxis for HIV infection must begin in the hours following exposure.

While a 48-hour limit seems "reasonable" if maximum effectiveness is to be hoped for, the animal models show that the chances of full effectiveness begin to diminish after the first 8 hours[3]. The leadtime before the results of a serological test for HIV can be obtained, although variable from one establishment to another, is usually two to three hours. Prophylactic treatment can then be prescribed under the best conditions, given the state of current knowledge.

The need for urgent action in providing prophylactic treatment is thus unquestionably established by the advances both in diagnostic resources (which now enable diagnosis within a few hours) and **the treatments available for HIV infection**, which are now very effective in this type of case.

B) THE NECESSITY FOR THE PRELIMINARY DETERMINATION OF THE SOURCE PATIENT'S SEROLOGICAL STATUS

Although the **urgent character of prophylactic treatment** following an accident involving exposure to blood has thus been firmly established, the need to determine HIV status before proceeding with prophylactic treatment must nevertheless be examined. **The conclusion is in fact that such determination appears to be an essential pre-requisite for prophylaxis**.

Is it possible to have reservations as to the necessity of this preliminary procedure? Might it not be possible to argue that the injured member of staff can undergo prophylactic treatment until the patient is again in a fit state to give his or her consent to screening? It is difficult to regard these reservations as entirely justifiable.

Firstly, because the administration of prophylactic antiretroviral treatment is not a procedure without certain consequences, given the constraints and side effects possibly entailed, and it is even more problematic to decide to go ahead with such treatment, without even knowing if the risk of HIV infection is a real one, given that the probability of infection due to a needle puncture is low (around 0.3%).

Secondly, because it is important to arrive at a clear position valid in all the circumstances considered here. It is inadvisable, therefore, to make distinctions based on the number of hours during which the patient is incapable of responding to a screening proposal (see the third parameter below). The need for urgent action must be evaluated in each case by the practitioner prescribing the test, who must decide on the advisability of waiting until the patient is in a position to understand what is happening (the accidental exposure to blood and the need to determine the patient's HIV status) and to consider the proposal for a screening test.

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[1] Cf. DGS/DH/DRT/DSS no. 98-228 of April 9 1998 *concerning recommendations for implementation of an antiretroviral treatment following exposure to the risk of HIV infection*. This circular, like that of April 20 1998, *concerning prevention of the transmission of infectious agents in the blood or body fluids in connection with the provision of healthcare care in hospitals* (DGS/DH no. 98-249), which also deals with the risk of transmission of HBV and HCV. In so far as, given the current state of the knowledge, no emergency treatment is recommended in the event of the risk of the transmission of these two viruses, the present report deals with the risk of HIV infection alone.

[2] Cf. *The treatment of HIV 3 infection / early diagnosis, antiretroviral treatment after HIV exposure and screening. Report of the working group to the Director General of Health on early diagnosis for HIV infection (November 1997)*, Ministry of Employment and Solidarity, Secretary of State for Health, HIV/AIDS series, CFES, February 1998.

[3] Cf. appendix 3 of the abovementioned circular of April 9, 1998: 'Protocol for antiretroviral treatment following exposure to HIV, and follow-up'.

C) IGNORANCE OF THE PATIENT'S SEROLOGICAL STATUS AND THE LEGAL DUTY TO OBTAIN INFORMED CONSENT.

The other two parameters are the source of the **problematic nature of these situations**. Firstly, ignorance of the source patent's HIV status results in prophylactic treatment being started immediately for the healthcare professional's benefit, although this would not have been prescribed if the source patient's negative status had been known. Secondly, the patient's specific medical condition prevents a screening test being offered to him, as testing for serological status presupposes that the person concerned has been previously informed and given his or her consent, in accordance with the legal framework governing screening procedures.

The legislation and regulations applicable to HIV screening policy indicate, both generally and for hospitals in particular, that **HIV screening cannot be performed without the patient's consent.**

- **From the general point of view**, screening is based on the dual principles of willingness and confidentiality. In a circular dated January 29, 1993, the General Health Directorate restated that "voluntary screening for HIV infection is an essential factor in the fight against AIDS. Such screening is aimed at encouraging individuals to behave in a manner likely to prevent infection, and to provide those who are HIV-positive with complete medical treatment at as early a stage as possible'[4].

France, like all western countries, has opted for "a policy of personal accountability based on personalized information/advice and voluntary screening". This policy has proved its worth. In the case of prenatal and prenuptial tests for example, a law passed in 1993 decided, after long debate but in accord with the views of the National Aids Council[5], that a screening test should be "offered" to (and not imposed on) women and future spouses[6]. Screening is in fact compulsory only for donations of blood, organ, tissue, gametes and milk.

- **In the specific case of hospitals** (in the public and private sectors), the circular of October 28, 1987 lays down the terms applying to HIV screening of patients who are hospitalised or receiving treatment in hospitals.

Firstly, generalised HIV screening (or the systematic prescription of HIV tests) is prohibited apart from the special case of the abovementioned donations. Secondly, the test can be offered to patients, especially in certain departments such as surgery, gynaecology/obstetrics, or those where endoscopic explorations are performed. Thirdly, the test must be offered in compliance with three "fundamental and mutually complementary rules", which apply generally to all screening procedures:
a) Prior information and unforced consent,
b) Feedback, in a medical interview, on the test result (positive or negative)[7] once it becomes available,
c) Provision to the patient of all information on suitable medical treatment and welfare facilities.

In the past, the authorities have had to remind hospitals of the necessity of complying with these three rules, due to repeated screening without the knowledge of the individuals concerned, or indirectly obtaining their consent (the screening test is already ticked in the list of examinations to be carried out before an operation, for example).

In the light of these provisions, it is essential that the patient should be informed and give his or her consent prior to the test. The hypothetical situation in which the patient cannot reply to the offer of screening is not clearly and explicitly addressed in the legislation. The law therefore does not provide for an exception to the generally applicable principles in these specific circumstances.

The impossibility of obtaining the source patient's consent due to his or her medical condition (coma or prolonged loss of consciousness) makes it difficult for healthcare professionals to reach a decision, torn as they are between the need to know the source patient's HIV status, and compliance with the law.

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[4] Cf. DGS circular no. 09 of January 29, 1993 *concerning anonymous screening without charge, and screening without charge for detection of Human Immunodeficiency Virus.*

[5] Cf. The Report following the Opinion of December 18, 1991 on obligatory or systematic screening of HIV. In 1992, the High Committee of Public Heath and National Advisory Committee for Ethics in the life sciences and health, stated, as did the National Aids Council, that it was against the compulsory screening of pregnant women, and those about to be married, The French Medical Association and the National Medical Academy said that they were in favour of such screening.

[6] Law no. 93-121 of January 27, 1993 concerning various social order measures, Article 48.

[7] The circular of 1987 provides for a medical interview only if the result was positive. However, new circulars on "good screening practice", have extended this provision to negative results (for example, circular DGS/DH/DGS no. 98-423 of July 9 1998 *concerning the missions and goals of anonymous HIV screening without charge, or HIV screening without charge.*

D) EXCEPTIONAL AND PROBLEMATIC CIRCUMSTANCES: THE PATIENT'S MEDICAL CONDITION

The third and last parameter defining the type of situation considered here is that **the patient is prevented from responding to the offer of screening** by a constraint which can be defined in medical, rather than psychological, terms.

It must be emphasised that the strict application of universal protection rules by hospital medical teams (in both public and private sectors) should make it possible to limit the number of cases of accidental exposure to blood.

2) SCREENING CONSIDERATIONS IN HOSPITALS, IN EXCEPTIONAL AND ROUTINE SITUATIONS.

The National Aids Council thus considers it reasonable, given the urgency of prophylaxis for healthcare personnel exposed accidentally to blood, to perform the test without the patient's consent in the exceptional circumstances which have been described, and only in these circumstances, in the interests of the healthcare professional victim who has been accidentally exposed.

The National Aids Council, in agreement with all those who gave evidence before its medical committee, considers that it may be a matter of urgency for the member of healthcare staff to determine the source patient's HIV status without delay in order to confirm the reality of the risk of HIV infection and prophylactic treatment administered, if required.

However, the National Aids Council considers **that screening without the patient's consent is a practice that must be prohibited in cases where the patient has previously expressed his opposition to a test of his HIV status**. However, it also considers that it is particularly important that **the patient should be persuaded to give his consent to such a test by means of discussion**.

In addition, the National Aids Council points out that a negative result to screening is not a complete guarantee that the source patient is free of infection, due to the time lag between HIV infection and seroconversion, (serological window). It is in the interest of the healthcare professional exposed to the risk, and also in that of the patient, that a further test should be carried out three months after the first, with the patient's consent.

Lastly, the National Aids Council emphasises **that such a conclusion is admissible only if two conditions are met**, these relating respectively **to screening in exceptional situations** (1) and **screening in routine situations** (2).

1. In the first case, the other exceptional rules for screening which apply in hospitals must be applied in the emergency situations set out here. A hospital department must comply strictly with the rules governing screening whenever it is faced with this type of situation, namely:
- Prescription of HIV screening of the source patient by a doctor, who must not be linked to the healthcare professional accidentally exposed to the patient's blood,
- Delivery of the test result to the source patient, whatever this may be, in the context of a medical interview.
- If the result is positive, complete information on medical and welfare treatment and facilities must be provided to the source patient, along with, where applicable, a proposal for the provision of treatment.

Where the implementation of the above rules is concerned, the hospital department should where necessary request the assistance of a doctor or a medical team with experience in the domain of HIV/AIDS.

2. Secondly, and **more generally, the hospital concerned must apply a screening policy which complies with the existing regulatory framework**. It must pay particular attention to ensuring that its departments, when carrying out their screening activity, comply with the dual obligations of informing the patient in advance and obtaining his or her informed consent.

In other words, **the National Aids Council, concludes that no screening tests without the knowledge of the patient can be tolerated, other than in the exceptional circumstances defined above**.

OPINION AND RECOMMENDATIONS

In the light of the law as it stands at the present time, which does not state that the patient can be represented by another person in the majority of cases, the National Aids Council makes the following recommendations.

3. In emergencies, which are very rare, presenting the following three characteristics :
- firstly, a healthcare professional has suffered an accident involving exposure to blood,
- secondly, the source patient's HIV status is unknown, and the patient has not previously refused screening,
- thirdly, the source patient's medical condition, such as a coma or a prolonged loss of consciousness, prevents any response to the offer of screening,

the source patient's consent to screening for HIV infection in hospitals (public or private) need not be required.

These emergency procedures take account of the possibility of ensuring maximum effectiveness of the treatment HIV infection in healthcare professionals, since they involve starting the treatment as early as possible. Such situations must remain the exception.

4. If such circumstances should occur, the hospital department must comply meticulously with the rules governing screening: the prescription of the test by a doctor, the delivery of the result to the source patient in a medical interview, and, if the result is positive, making all the information available to the patient on medical and welfare treatment and facilities, along with the offer to provide treatment as such.

The National Aids Council strongly recommends that the hospital department should request the assistance of a doctor (or a medical team) experienced in the HIV-AIDS domain for the implementation of the above rules.

5. Apart from these emergency situations, the essential rules which apply to screening in hospitals, notably the dual obligations of informing the patient in advance and obtaining his or her informed consent, must be strictly applied in the hospitals concerned.