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NOTE EQUIVALENT TO AN OPINION

SCREENING

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NOTE EQUIVALENT TO AN OPINION ON COMMERCIALISATION OF HIV SELF-TESTS

In a letter dated 3 May 2004, the National Advisory Committee on Ethics, to which the Director General on Healthcare had referred the issue of possibly "making viral and genetic self-test kits available to the public", sought Conseil National du SIDA's opinion on the HIV-related aspects of the matter, so that a joint stance could be taken on the matter. Already referred to once in 1998, the CNS underscored, in its opinion[1] , the need for medical supervision in all forms of testing for HIV-contamination. Today, HIV-screening kits can be purchased on the Internet.

The expression "self-test" refers to a screening kit for use in the home. Such kits can come in one of two forms[2] : either a self-sampling test, in which the person takes his own blood sample using a kit, in order to send it to a laboratory for analysis; or a self-analysis test, in which the self-sampling kit comes along with material that allows the individual to view his result within 20 to 30 minutes. It is the latter "self-test" – the self-analysis test – that the CNS focuses on more specifically in this opinion. Three questions arise when it comes to making such kits available to the public: the reliability of the results provided; the limits of self-analysis; and unethical use of the kits in such a ways as to foster coercive or discriminatory practices.

1..THE RELIABILITY OF SELF-ANALYSIS TESTS

Though self-tests have not yet received the EC label[3] , the results they yield seem increasingly reliable. The latest trials involving self-analysis tests, as carried out by the Centers for Disease Control (CDC) AIDS Division, in March 2004, show that they, under the best circumstances, they prove 99.8% sensitive and specific, provided that the test is perfectly conducted[4] and that the interval required for antibodies to appear[5] , known as the "sero-conversion window" is taken into account. Such results remain inadequate, however, to fully inform individuals, especially in countries where prevalence is low[6] . With a test posting specificity[7] and sensitivity[8] levels of 99.8%, taking an adult population where the infection's prevalence is around 2 per 1 000, the percentage of false-positives would be around 50%. In other words, seeing a positive result, one out of every two people would wrongly believe himself or herself a carrier of the AIDS virus. This demonstrates that any positive result must be confirmed by a standard test. A test result alone is not enough to establish an individual diagnosis of HIV-contamination for a given person.

2..THE LIMITS OF SELF-ANALYSIS

In its 1988 opinion, the CNS emphasised that this type of self-test offers the ease and comfort of home-sampling. However, the self-test's drawback lies in the absence of pre- and post-test counseling sessions, intended first to inform about the risks of contamination and the ways of preventing them, and secondly, to explain the meaning of the test and its result. The said sessions

[1] Opinion on "the opportuneness of making home HIV-screening tests available on the French market", 19 June 1998.

[2] Such kits, available online, are based only on blood samples, not saliva.

[3] This label is required prior to any form of commercialisation in pharmaceutical outlets, as stated in the 1 March 2001 Order n° 2001-198 on the transposition of Directive 98/79/EC of the European Parliament and Council of Europe, dated 27 October 1998 regarding medical in vitro diagnosis devices.

[4] In the CDC (Centers for Disease Control) study on the ability of people with no laboratory experience to carry out a self-test, only 9% failed to successfully carry out the test.

[5] The median interval is 22 days.

[6] Number of cases of new and already-reported illness in a given population, compared to population studied.

[7] The specificity of a diagnostic test is its ability to yield a negative result if there is no illness.

[8] The sensitivity of a diagnostic test is its ability to yield a positive result if there is illness.

form the backbone of the screening system in France. Furthermore, they make it possible to provide support and follow-up to the person tested, particularly important when a positive result is announced.

In order to become an integral part of an individual or group healthcare system, screening for HIV-contamination requires a direct relationship with a physician. Self-tests provide only a result which, as shown above, cannot provide a definite and final diagnosis. As the CNS has already pointed out, self-analysis tests do not encourage the subject to enter the healthcare system, leaving the user alone with the results.

3..UNETHICAL USE

When a test is easy to use, regardless of how reliable it is, the risk of it being used in coercive situations is greater. For instance, the test could be performed by employers during the hiring process, insurers prior to signing a contract, police officers during checks, etc. Another use – to be feared – is that prior to sexual interaction, to justify not using means of prevention, thereby heightening the current surge in sexually transmitted diseases.

The development of self-tests on the other side of the Atlantic is due in particular to the fear of losing one's anonymity. In France, where the law guarantees confidential access to screening and anonymised data processing, screening kits are not as valuable.

CONCLUSION

Self-testing, in addition to offering low diagnostic value, cannot be integrated into a broader prevention policy. Moreover, it leaves individuals to face positive results on their own, thus not fostering their seeking medical and social care, and creates risk of inappropriate use, going against individual rights. Above and beyond HIV self-testing, the objections raised in this opinion could also apply to other self-tests.

For public health, medical, social and ethical reasons, the CNS warns against the distribution of self-tests for HIV-infection screening.