OPINION ON OVER-THE-COUNTER HIV TESTS

ADOPTED BY THE FRENCH NATIONAL AIDS COUNCIL
(CONSEIL NATIONAL DU SIDA) ON 20TH DECEMBER 2012

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OPINION
SCREENING

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This Opinion was unanimously adopted by all members of the National AIDS Council, present at the plenary session held on 20th December 2012.

The French National AIDS Council (Conseil national du sida - CNS) is an independent, consultative French agency that was set up in 1989. It comprises 24 members: specialists working in the field of HIV/AIDS, representatives of civil society, and members of associations.

The CNS delivers opinions and recommendations on the full spectrum of issues that society faces as a result of HIV/AIDS. These papers are addressed to the French authorities and to all those involved in or concerned by the epidemic.

It is the intention of the CNS to participate in this manner in the development of public policy, within a framework that promotes respect for fundamental ethical principles and human rights.

For more information, please visit: www.cns.sante.fr

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PREAMBLE

In a letter dated 8th August 2012, the Minister for Health and Social Affairs asked the French National AIDS Council to produce a new opinion on the issues relating to the marketing of over-the-counter HIV tests.

Over-the-counter HIV tests are single-use tests to detect HIV-1 and HIV-2 antibodies with the following characteristics:

- They are carried out by the persons themselves with no need for third-party involvement;
- They can be obtained over the counter and do not require any specific instrumentation beyond what is provided in the kit;
- There are at least two stages to the test: self-sampling, then self-analysis of the result;
- They can be used on two types of bodily fluids: Either a fingerstick capillary blood sample, or gingival crevicular fluid from an oral swab;
- They are rapid tests which provide a result in a short timeframe, usually less than thirty minutes;
- The results obtained must be confirmed by laboratory-based testing.

In the United States, home-based HIV tests for self-sampled capillary blood have had marketing authorisation since 1996. More recently, an oral swab over-the-counter HIV test was authorised in July 2012.

No over-the-counter HIV tests have been authorised for sale in the European Union under regulations governing medical devices.

In two previous Opinions published in 1998 and 2004, the French National AIDS Council expressed its reservations regarding over-the-counter HIV tests. Whilst acknowledging that they may increase screening amongst populations with no access to preventive care or who are wary of conventional testing, the Council considered that there were a number of disadvantages to these tests, in particular:

- insufficient accuracy;
- the absence of the support required in the event of a positive result;
- no pre or post-test consultation;
- the possibility of misuse under coercion.

In light of developments since these Opinions were published, notably in terms of home-based testing techniques and provisions for screening in France, the French National AIDS Council felt it was time to reconsider its reservations and more broadly speaking, examine the ethical, strategic and organisational issues that would arise should over-the-counter HIV tests be made available in France.

To this end, the French National AIDS Council set up a commission to hold hearings and review the literature. The commission has drawn up a Report based on this work. Prior to the vote to adopt the Opinion, the Council shared its initial conclusions with the National Ethics Advisory Committee (CCNE), also solicited for an Opinion on this matter, at a joint working meeting.

THE FRENCH NATIONAL AIDS COUNCIL HAS EXAMINED AND TAKEN INTO CONSIDERATION THE FOLLOWING POINTS

THE OPPORTUNITY TO PROVIDE SCREENING WHICH IS BETTER ADAPTED TO THE CURRENT EPIDEMIOLOGICAL, MEDICAL AND SOCIAL CONTEXT OF HIV CONTROL IN FRANCE

REDUCING THE NUMBER OF LATE PRESENTERS AND THE PROPORTION OF PEOPLE WITH HIV UNAWARE OF THEIR STATUS

Today there is a general consensus amongst HIV/AIDS stakeholders that earlier, more frequent screening is required to optimise individual care management for people with HIV, and prevent HIV transmission amongst the general population.

It has been demonstrated that the later a HIV infection is diagnosed the greater the risk to the patient's health. Indeed, the early use of the highly active combination antiretroviral therapies currently available improves their effectiveness. In terms of personal health, reducing the lapse of time between infection and treatment is a determining factor for successful treatment.

On a population basis, delayed screening contributes to the "hidden epidemic" which plays a significant role in the continuing spread of the epidemic. In terms of public health, late screening and consequently late access to the medical and psychosocial care system hinder the prevention of secondary HIV transmission. On the one hand, it has been shown that if people are aware of their infection they reduce their at-risk behaviour. On the other hand, it has now been demonstrated that the reduction in viral load in genital secretions achieved using antiretroviral treatment, greatly reduces the risk of sexual transmission. The highly effective preventive effect treatment confers is considered to be an essential lever for reducing the number of new infections in the population, a pre-requisite for stemming, and ultimately reversing, the spread of the epidemic.

EXPANSION AND DIVERSIFICATION OF SCREENING OFFER

Approximately 5 million HIV serologic tests are carried out each year in France resulting in the diagnosis of about 6,000 cases of HIV. These figures have been stable for the last few years. It is important to note that 77% of serologic tests are carried out in private laboratories as opposed to 16% in hospital settings and 7% in the dedicated CDAG (free and anonymous screening settings). The support provided for patients screened in private laboratories often falls short of current recommendations regarding best practices. This casts doubt on the real impact of these recommendations, given that almost 8 out of 10 people are tested in these settings.

This leveling off in the number of new cases detected, along with new screening-related issues, infer that improving the quantitative and qualitative aspects of the screening system is now a priority for public policy against HIV/AIDS, notably under the 2010-2014 National HIV/AIDS and STI Strategy Plan (PNLS), which focuses public action on three main areas of intervention:

- Reinforcing screening offer by health care workers within the healthcare system, by increasing the opportunities for health professionals to offer testing in the various contexts in which people seek out health care;
- Expanding voluntary screening, by developing innovative community-based screening schemes, implemented by not-for-profit structures targeting high incidence populations, using rapid HIV antibody tests;
- Overhauling dedicated schemes for free, anonymous screening by reorganising the network of CDAG and CIDDIST (free STI screening and care settings) and developing sexual health centres.

However, the implementation of these different interventions is patchy and too recent to allow for detailed assessment. It is therefore difficult to assess their impact in terms of prevention effectiveness. The latest available data (from 2011) show a modest increase in the number of serologic tests carried out (+4%), but no increase in the number of cases of HIV infection detected, compared to the previous five years.

Without pre-empting the quantitative and qualitative outcomes of the actions undertaken, it is relevant, given the importance of the issues in question, to continue with and develop the strategies to expand and diversify screening provision. An analysis of the factors which discourage people from soliciting screening shows that progress can be made by developing additional screening strategies, which are complementary and better-adapted to the full range of people's needs. In this context, over-the-counter tests may well constitute a means to expand the range of screening tools on offer, notably for people the current system does not reach.

IMPROVED PERFORMANCE OF OVER-THE-COUNTER HIV TESTS, THEIR ROLE IN THE SCREENING SYSTEM AND THE BENEFIT/RISK RATIO

THE IMPROVED PERFORMANCE OF THE OVER-THE-COUNTER HIV TESTS

In the United States the over-the-counter oral swab OraQuick® In-Home HIV test was approved by the Food and Drug Administration (FDA) on 3rd July 2012 after an extensive evaluation process.

The results of this evaluation demonstrated the test's performance. Its specificity, i.e. its ability to give a negative result when the infection is not present was shown to be 99.8%, which is highly satisfactory. Its sensitivity, i.e. its ability to give a positive result when the infection is present was shown to be 92.9%, which is less than satisfactory. It should be noted that an evaluation of the same OraQuick® test carried out by a team of French researchers reported an even lower level of sensitivity, at 86.5%.

The evaluation of this over-the-counter HIV test also investigated whether it was sufficiently simple to use and if comparable performance could be achieved in the hands of untrained users. A small number of cases were recorded in which the user obtained no result (56 out of 4,465). The messages regarding eligibility for the test, its performance and use were well understood by the participants.

THE ROLE OVER-THE-COUNTER HIV TESTS COULD PLAY IN THE SCREENING LANDSCAPE

Studies carried out in the United States and in France into people's preferred screening methods have shown high acceptability for rapid, non-invasive tests. In these studies, there was a preference for rapid tests and over-the-counter HIV tests over conventional tests; and for saliva tests over blood tests. The most commonly cited reasons for this were the convenience, rapidity and confidentiality of the tests. Participants did however express concerns about the lack of support when obtaining the test result and this may constitute a barrier to use.

Men who have sex with men (MSM) and young people were the most interested in over-the-counter tests. Home-use tests could constitute a suitable form of screening for certain MSM who keep their sexuality secret and/or who live in small towns or periurban or rural areas where screening is less readily available and anonymity more difficult to ensure. They may also be helpful for MSM who do not consider themselves to be part of the gay community and are therefore less receptive to targeted prevention messages. Home-based testing could also be of interest to the partners of people who use over-the-counter HIV tests; the latter could offer the former information regarding the issues surrounding, and benefits of, home-based testing and screening. In addition to MSM, other populations with a high risk of HIV transmission may have a legitimate interest in using over-the-counter HIV tests, in particular migrants, sex workers or intravenous drug users.

For these populations, and others, home-based testing could offer a means to privately access screening. As home-use tests must be initiated by the person themselves, it also encourages them to take personal responsibility for their health. This is both in the individual's own interest but also serves the collective interest to increase screening.

Certain circumstances may however limit the advantages of home-use tests. First of all, a high retail price of over-the-counter HIV tests may restrict their use amongst certain target populations. A significant number of people who are both financially vulnerable and exposed to the risk of HIV transmission will not have access to this form of testing. Furthermore, the unsupervised use of over-the-counter HIV tests means that some of those who self screen will not have their test confirmed or subsequently access medical care. Preliminary data collected from over-the-counter HIV test users already shows there are genuine difficulties regarding access to care. Finally, the over-the-counter HIV tests currently authorised have unsatisfactory levels of sensitivity meaning there is a risk, albeit a small one, that a true positive may not be detected.

THE INDIVIDUAL AND COLLECTIVE BENEFIT/RISK RATIO

Determining the benefit/risk ratio for the introduction of over-the-counter HIV tests is a complex exercise. The risks cover the number of false negatives amongst people who opt for home-based testing and the number of cases of HIV/AIDS transmission that are not avoided due to these false negatives, as well as people not accessing care and not changing their at-risk behaviour. The benefits cover the number of new cases of HIV diagnosed and the number of transmissions averted.

The assessment of home-use tests is based on several hypotheses: Test sensitivity, its use by a given population (MSM, high-risk heterosexuals, low-risk heterosexuals), the percentage of these populations diagnosed as HIV positive using an over-the-counter HIV test who would not have been diagnosed through conventional screening mechanisms, and the number of transmissions averted in relation to the number of new infections diagnosed. Based on these hypotheses the FDA estimated that it would allow for 44,000 new cases of HIV infection to be diagnosed and 4,000 new cases of infection prevented in its first year on the market.

The hypotheses and model retained by the FDA can be used to assess the benefit/risk ratio of introducing home-use tests in France and allow to state the following: First, it is estimated based on the FDA hypotheses that the introduction of over-the-counter HIV tests in France would make it possible to diagnose 4,000 new cases of HIV and avoid 400 new cases of infection. Second, the benefits of self-testing are greater than the risks, regardless of the plausible hypothesis retained. The only situation in which an unfavourable benefit/risk ratio is obtained is when extreme, highly improbable hypotheses are used.

CONSEQUENTLY, THE FRENCH NATIONAL AIDS COUNCIL RECOMMENDS

Given the vital need for earlier screening in France, the characteristics of the over-the-counter HIV tests, their potential role in the overall screening system and their benefit/risk ratio, **the French National AIDS Council is favourable to making over-the-counter HIV tests available**.

In order to ensure the maximum effectiveness and safe use of this new screening tool, the Council also makes the following further recommendations.

1. Over-the-counter HIV tests should form **an additional and complementary offering** within the existing range of HIV screening services. Over-the-counter HIV tests should not substitute to existing screening settings as the result obtained using a home-use test needs to be confirmed with a conventional laboratory-based test. Furthermore, home-use tests should be backed up with a range of prevention measures, in addition to confirmation of the test result, in particular screening for other sexually transmitted infections.

2. **Over-the-counter HIV test should be made available through a variety of distribution channels, adapted to different people's needs**.

    2.1. **For the general public, home-use tests should be made available over the counter in pharmacies and on the internet**. They should be made available online for people wanting to make a discreet purchase. This will also guarantee a supply of safe, reliable over-the-counter HIV tests amongst the multitude of counterfeit tests or tests without patient information leaflets in French currently available for purchase online from other countries.

    2.2. **Home-use tests should also be offered to key populations with a higher risk of HIV infection, defined as high priority** under the most recent national HIV/AIDS and STI Strategy Plan. Over-the-counter HIV test distributions should also be organised **by the appropriate bodies** (not-for-profit organisations, information, screening and diagnosis settings, general practitioner) based on the experience acquired with rapid HIV antibody tests. The expected cost of these over-the-counter HIV tests should be taken into account when looking at how they should be made available.

3. **It is also important to establish the conditions for use which offer the best possible levels of support for over-the-counter HIV test users**.

    3.1. The support provided for users should allow them to use the new tool correctly, **freely and autonomously**, i.e. with no constraints or external coercion.

    3.2. **Various documents must be provided** with the home use test in order to offer the required support. This documentation should specify who is eligible for the test, the practical instructions for use i.e. for taking the sample and then analysing the result, how to interpret the result, and, crucially, the limitations of the tests, notably in relation to the seroconversion window period. The documents should also provide information on the importance of confirming the test result and accessing care. It should provide contact details for relevant structures and refer users to **different remote support services**. These services should provide counseling, assistance, support and information through a variety of channels suited to the different populations concerned, and should be available 24/7: A dedicated internet site optimised for mobile use, a call centre, email, internet forums and chat rooms.

4. **It is vital that a wide spectrum of stakeholders, beyond the traditional HIV/AIDS actors, is mobilised to oversee the marketing and distribution of over-the-counter HIV tests**.

    4.1. Not-for-profit HIV/AIDS organisations and other prevention professionals will be able to provide expert input to design over-the-counter HIV test support tools and make them available to target populations.

    4.2. However, the Council considers it necessary to mobilise not-for-profit and institutional stakeholders who do not exclusively work in the field of HIV/AIDS control, but who may nonetheless be able to reach at-risk populations who currently receive no, or insufficient screening, as well as the wider population.

5. **Alongside the introduction of over-the-counter tests, screening and the related issues and methods should be promoted more generally** in order to strengthen combination prevention.

6. One year after the introduction of over-the-counter tests, **an evaluation should be carried out** to examine the conditions in which this process has taken place using data collected from the various stakeholders involved in distributing the tests and supporting users.

APPENDICES

LETTER OF REFERRAL

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RÉPUBLIQUE FRANÇAISE

Ministère des Affaires Sociales et de la Santé

La Ministre
CBI/NL D12-4315

Paris, le - 8 AOUT

La ministre des affaires sociales et de la santé

à

Monsieur le Président du Conseil national du Sida (CNS)

Objet : Autotests de dépistage de l'infection au VIH

Une réflexion sur l'opportunité de la mise sur le marché d'autotests pour le dépistage de l'infection au VIH a été menée entre 2004 et 2007 par le ministère chargé de la santé. Elle a abouti à des avis défavorables du Comité consultatif national d'éthique (CCNE) et du Conseil national du Sida (CNS).

Les principaux arguments avancés étaient d'ordre éthique et médical, avec notamment la fiabilité des tests, le risque lié à la disparition des entretiens pré et post-test permettant une information-conseil visant à l'ajustement des comportements préventifs, à la suppression de la possibilité d'un soutien immédiat et d'une orientation vers le soin en cas de positivité. L'AFSSAPS avait par ailleurs soulevé les difficultés d'utilisation et d'interprétation que posait l'utilisation de ces tests par des non professionnels.

Depuis, le contexte du dépistage du VIH a notablement évolué en France comme dans le monde.

L'utilisation de tests rapides d'orientation diagnostique (TROD) pour le VIH a été réglementée en France en 2010 : ils peuvent être désormais utilisés tant par des professionnels de santé en milieu médicalisé que dans un cadre associatif non médicalisé par des personnes ayant été formées à leur usage.

Le 3 juillet dernier, l'agence américaine des médicaments (FDA) a autorisé la mise sur le marché d'un TROD VIH (Oraquick®) en tant qu'autotest sans supervision médicale. Ce test sera en vente libre à partir d'octobre 2012 dans plus de 30.000 points de distribution aux Etats-Unis et il est très probable qu'on le retrouve après cette date, accessible sur internet.

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En France et dans les principaux pays européens, aucun autotest conforme à la réglementation européenne (marquage CE) ne semble être sur le marché jusqu'à maintenant.

Dans ce contexte évolutif, j'aimerais pouvoir disposer d'un nouvel avis de votre Conseil sur les problèmes posés par la commercialisation d'autotests de dépistage de l'infection au VIH.

Je vous informe que j'ai en parallèle saisi de ces questions le Comité consultatif national d'éthique, avec lequel il m'apparaîtrait important que vous puissiez travailler. Un point technique de l'Agence nationale de sécurité du médicament et des produits de santé sur ce sujet est également attendu pour septembre.

Je souhaiterais pouvoir disposer de l'avis du CNS sur cette question d'ici la fin décembre 2012.

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11.10.2012
- **Gilles Pialoux**, MD – Infectious Diseases (Hôpital Tenon, Paris)
- **France Lert,** MD – Epidemiologist (Inserm)

18.10.2012
- **Tim Greacen** – Psychologist (Hôpital Maison Blanche)

25.10.2012
- **Act Up-Paris** – Jérôme Martin, Arthur Vuattoux (Vice-President)
- **The WARNING** – Georges Sidéris (President), Nicolas Charpentier
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