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PUBLIC HEALTH GUIDELINES

HIV infection screening in France

Screening Strategies

EXECUTIVE SUMMARY AND GUIDELINES

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The guidelines and the executive summary of this evaluation are available for download at
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Abbreviations

The abbreviations and acronyms used are explained below to facilitate reading (table 1).

Table 1. Commonly used abbreviations

Abbreviation	Meaning
BEA	Blood Exposure Accident
Afssaps	French Health Products Safety Agency
ANRS	French AIDS and Viral Hepatitis Research Agency
CDAG	Free, Anonymous HIV Screening Centre
CDC	Centres for Disease Control and prevention
CIDDIST	Diagnosis, screening and information centre for sexually transmissible diseases
CNR	National Reference Centre
CNS	French National AIDS council
COREVIH	Regional coordination for the fight against human immunodeficiency virus
DFA	French Departments of America
DGS	French General Health Directorate
ECDC	European Centre for Disease Control and prevention
ELISA	Enzyme-Linked Immunosorbent Assay
FHDH	French Hospital Database on HIV
MSM	Men who have Sex with Men
Inpes	French Institute for Prevention and Education for Health
INVS	National Health Monitoring Institute
STI	Sexually Transmissible Infection
WHO	World Health Organisation:
RST	Rapid Screening Test
IDU	Injectable Drug User
HIV	Human Immunodeficiency Virus

Glossary

Counselling: Individually-tailored advice and information to help people make decisions, resolve problems and cope with crises obliging them to make a series of changes for which they do not necessarily feel prepared. In the field of health and HIV, counselling is given to single individuals or groups. It must be provided by professionals or peers who have received a minimum of training in conducting counselling interviews and about the health topic for which the user or patient must acquire knowledge or specific skills.

Opt-out screening: Screening after informing patients that the test will be performed unless they decline it.

Primary care: According to the French hospital reform bill n°2009-879 of 21 July 2009 concerning patients, health and territories, primary care comprises "1° the prevention, screening, diagnosis, treatment and follow-up of patients; 2° The dispensing and administration of medications, products and medical devices, as well as pharmaceutical advice; 3° Referral to other professionals in the healthcare system and medico-social sector; 4° Health education. Health professionals, including general practitioners (…), as well as health centres contribute to the primary care offer, in collaboration and, where applicable, within the framework of co-operations organised with health, social and medico-social institutions and services.

Combined ELISA test: An ELISA test is said to be combined when it permits the simultaneous detection of anti-HIV-1 and anti-HIV-2 antibodies and p24 antigen.

Rapid screening test (RST): A rapid screening test is a single test, with subjective interpretation of the result, that is simple to perform and designed to give a result in a short time (generally less than 30 minutes) when performed at point of care. It may be performed on whole blood, saliva, plasma or serum depending on the diagnostic matrix claimed by the manufacturer for its product. It permits the detection of anti-HIV-1 and anti-HIV-2 antibodies.

Future evolution of the HIV screening system and strategies in France

The General Directorate of Health (DGS) asked the French National Authority for Health (HAS) to update good HIV screening practices according to recent evolutions in screening tests and the HIV epidemic. At the request of the DGS, the first section of these public health guidelines about screening tests and discussing in particular the place of RSTs in HIV screening strategies was published in October 2008. The present document discusses questions concerning the evaluation of possible changes in the screening strategies. However, the HAS points out that these two sections should not be dissociated as together they comprise a global response to the challenge of HIV screening in France.
After analysing the current French situation concerning screening for HIV infection and using information gained by a literature review and the model developed in the French epidemiological setting in order to evaluate the effectiveness and efficiency of different HIV screening strategies in France, several potential pathways of change were explored. These concern the main routes of access to screening in France (individual voluntary screening and systematic screening) and do not discuss the two other strategies (mandatory screening and early detection of the clinical signs suggesting established HIV infection or AIDS1) which were excluded from the field of the present guidelines. The existing screening system was also re-examined in the light of the proposed changes in screening strategies.
The present document provides a synopsis of the rationale for the public health guidelines presented below.

1 Screening for HIV infection in France: current appraisal and future challenges

1.1 A few findings

1.1.1 Late HIV screening

Although there is a very high HIV screening activity at national level (5 million HIV tests performed in 2007, placing France second among the countries of Western Europe behind Austria, with a rate of 79 per 1000 inhabitants), HIV testing is still delayed in particular in certain population groups or individuals.
According to the data from the mandatory HIV/AIDS reporting system, over the 1997-2005 period, 47% of subjects diagnosed with AIDS were late testers. In addition, when the mandatory reporting data for HIV infection and AIDS in 2005 are compared, late screening (defined as concurrent diagnosis of HIV infection and AIDS) represented 48% of the number of cases of AIDS and 16% of new HIV diagnoses.
Likewise, using the same definition for late screening (diagnosis of HIV infection at the AIDS stage and/or CD4 T-lymphocyte count below 200/mm3), three studies on populations of subjects for whom the diagnosis of HIV infection was made between 1996 and 2005 estimated that the late screening rate was between 25 and 35% in France.

[1] On the contrary, the case of the early detection of signs of primary HIV infection is discussed.

Some factors responsible for this late screening were identified by analysing the data obtained from the mandatory HIV infection/AIDS reporting system: age over 40 years, foreign nationality (in particular sub-Saharan Africa) and heterosexual mode of contamination. Likewise, several characteristics were associated with late testing in French multicentre study cohorts: age 30 years or more, non-homosexual mode of transmission, migrant woman status, male sex, persons living as a couple and having children. Some of these factors may be used to identify late testers at risk who do not form part of sub-populations with the highest prevalence of HIV infection or the highest detection rate of positive HIV serostatus (cf. point 1.1.3 below).

1.1.2 Prevalence of undiagnosed HIV infection

This late screening is also shown by the prevalence of undiagnosed HIV infection. The latter was estimated in France by the French National AIDS Council from the total prevalence data and the hospital registered patients (FHDH database rectified using the estimated exhaustiveness rate of 50-60%). A mean estimate of 40,000 was proposed in 2005 for the number of infected persons who are unaware of their positive HIV serostatus (range between 18,000 and 61,000).

1.1.3 Heterogeneity of the epidemic of HIV infection in France

In addition, the epidemic of HIV infection continues to affect more particularly population groups and regions.
The epidemiology of HIV infection in France is characterised by a few major recent changes:

- An increase in high-risk sexual practices by MSM and the maintenance of high homosexual HIV transmission rates;
- The increase in the number of persons from sub-Saharan Africa infected by HIV;
- The absence of any sign of renewed transmission of HIV in IDU;
- The existence of large regional disparities, with the Ile-de-France and DFA being the most affected regions.

The epidemiological characteristics of HIV infection in French Guiana place this DFA in a generalised epidemic situation.

1.2 Demonstrated benefits of early screening

Although the individual benefits of screening for HIV infection were limited for a long time by the absence of effective treatments, the development of new therapies or means of prophylaxis has increased the importance of early diagnosis of HIV infection both at individual and community level.

The individual benefits of screening for HIV infection have become very clear since the availability of highly active antiretroviral therapies (HAART). In particular, the impact on mortality of late presentation to care (defined as diagnosis of HIV infection at the AIDS stage and/or with a CD4 T-lymphocyte count below 200/mm3) was demonstrated from the FHDH data for patients included between 1997 and 2005: the relative risk of death associated with late presentation to HIV care was estimated to be 13.2 during the first 6 months after inclusion in the database and remained significantly greater than 1 for the first 4 years after management, in comparison with early presenters.

Screening therefore permits the early institution of antiretroviral medication (combination therapy) with demonstrated effectiveness on the reduction of morbidity and mortality. It may also facilitate the implementation of appropriate early management for seropositive pregnant women in order to reduce the risk of vertical transmission (antiretroviral medication, prophylactic caesarean section, contraindication to breast-feeding). Prophylaxis of opportunist infections or vaccinations may also be proposed.
Lastly, screening may be used as a tool for prevention and to encourage changes in attitudes and behaviours.

At community level, the benefits of screening for HIV infection have also been underlined. Screening may reduce HIV transmission rates in two ways:

- Directly by reducing high-risk practices;
- Indirectly by identifying additional infected persons meeting the criteria for institution of HAART, which also leads to a decline in HIV infectivity.

Although there is little direct evidence for an association between screening and a reduction in HIV transmission, several epidemiological findings support a reduction in the risk of transmission of treated patients: the association between the reduction in viral load obtained by HAART and a reduction in infectivity; reduction in the number of new cases of contamination by HIV after widening the availability of HAART.
Moreover, according to different meta-analyses and systematic reviews, screening/counselling seems to be associated with a reduction in high-risk practices but only in seropositive individuals. It therefore appears to be an effective secondary prevention strategy.

1.3 The present screening system and its deficiencies

Deficiencies in the present screening system for HIV infection have been highlighted on the one hand by the finding of persistent late testing by population groups partly different from the sub-populations most affected by the HIV epidemic and the demonstrated benefits of early testing on the other. Designed and implemented at a time when the risks of stigma and discrimination directed against persons living with HIV/AIDS were particularly high and when the individual benefits of screening were limited by the absence of effective treatment, the organisation of HIV screening was based on specific principles, largely outside those of the traditional framework for fighting against transmissible diseases. Particular attention was therefore placed on the importance of voluntary participation and individual responsibility during the screening procedure and on the need for clearly expressed informed consent and the respect of confidentiality.
These principles led to the promotion of a voluntary screening policy for patients who had received advice and information from healthcare professionals and were referred for testing according to their exposure to a risk of infection. Systematic screening is only proposed with prior consent, to pregnant women during the 1st antenatal appointment and in case of imprisonment.
CDAGs (Free, Anonymous AIDS screening centres) form the cornerstone of the screening system and were designed as reference instruments of a public HIV prevention policy based on individual responsibility and the encouragement of voluntary testing. These centres were assigned the task of "*assistance in adopting personal attitudes of prevention, diagnosis, counselling and advice about appropriate management and support in maintaining long-term preventive behaviours against HIV transmission by affected persons*". In addition, the principle of free and anonymous care should facilitate access to screening, in particular for the most vulnerable and exposed populations.
The development of new therapeutic and prophylactic methods, technological progress in methods for screening and laboratory diagnosis, the persistent delay in screening in particular for groups not traditionally considered to be at risk of HIV infection and changes in

the underlying epidemiology all constitute challenges making it necessary to update HIV infection screening strategies. All these changes have lead to the reconsideration, both internationally and in France of the basic precepts of screening strategies for HIV infection.
In particular, some authors have supported the implementation of a new screening model with an end to the exceptionalist HIV-testing paradigm that forms the basis of the "traditional" screening approach. This has led to the recent publication of several guidelines and opinions recommending that screening is extended and proposed, on the initiative of health professionals, to the whole of the general population and not just to groups with high-risk behaviours or specific characteristics.
However, although new strategies must be tried out in order to overcome the deficiencies of the current screening system, the proposed changes must not compromise the respect of principles guiding HIV testing in France :

- The attention paid to the persons' rights (respect of confidentiality and entitlement to anonymity, counselling and informed consent) ;
- Guaranteed access to free screening through a diversified offer ;
- Promotion of the voluntary screening pathway.

2 Questions evaluated and methodological approach adopted

2.1 Questions discussed during the evaluation

Within the scope of this second focus of evaluation on the relevance of a change in the HIV screening system and strategies, several questions were upheld after an analysis of current challenges in screening and a clarification of the expectations of the DGS in relation to InVS, Afssaps and the CNS:

- Is it possible to identify sub-groups at risk to which screening must periodically be proposed? How often? In what structures?
- Should a screening test be proposed more systematically outside traditional risk-based screening? When? In what structures?
- Should counselling practices be changed in particular for pretest counselling?

2.2 The methodological approach adopted

2.2.1 Scope of the evaluation

Screening has been principally defined as the conduct of serologic tests in asymptomatic subjects or individuals with clinical symptoms suggesting primary HIV infection. Patients presenting clinical symptoms suggesting an established HIV infection or AIDS were excluded from the field of these guidelines.

The evaluation examined all possible screening strategies for HIV infection that may be used in France, except for mandatory screening. The following were therefore distinguished:

- Screening strategies involving the systematic proposal of screening to all subjects including subjects not considered to be exposed to a risk (called general population screening proposal);
- Risk-based strategies based on a targeted offer of screening for persons at high risk of infection (called targeted screening);
- Screening strategies based on individual voluntary screening on the initiative of any person wanting to know his/her HIV serostatus either after exposure to a risk or not.

The evaluation concerned screening for HIV infection by health professionals or trained individuals in subjects aged over 15 years, including pregnant women. Only systematic screening strategies were considered for pregnant women as such a strategy has clearly been shown to be successful and acceptable.

2.2.2 Evaluation criteria

After a re-examination of the benefits associated with screening of HIV infection, two major focus areas were distinguished.

Firstly, the current screening strategy mainly based on voluntary individual risk-based screening was confronted with the French epidemiological setting. An appraisal was therefore made of the epidemic of HIV infection and screening and prevention practices in France leading to a diagnosis of the HIV screening situation in France.

Secondly, the effectiveness, acceptability and efficiency of different screening strategies proposed by healthcare providers (change in targeted screening and proposed general population screening) were assessed.

2.2.3 Methods

The relevance of a change in screening strategies for HIV infection was assessed both on the basis of a systematic and critical review of the literature and by modelling.
The financial repercussions of implementing different screening strategies for HIV infection from the current strategy (budgetary impact analysis), in particular on the National Health Insurance budget, were not evaluated in this report because of uncertainties about how rapidly the proposed general population screening may be implemented.

A critical analysis of the literature was carried out by HAS project leaders and concerned 1) the benefits of screening and counselling, 2) targeted screening 3) the clinical benefits, acceptability and efficiency of the proposed general population screening.

Because of the variability of the results of international studies and the lack of a French study evaluating HIV infection screening strategies, a mathematical simulation was proposed to take into account specific features of the French situation. These modelling studies were conducted under the direction of Prof. Yazdanpanah, in partnership with InVS, CRESGE and HAS and associated INSERM, *Partners AIDS Research Centre* (*Harvard Medical School*) and *Yale School of Public Health* (the composition of the monitoring committee of these studies is presented in appendix 1).

The purpose of this study was to evaluate the effectiveness, cost, and cost-effectiveness ratio of the different screening strategies in France:

- Should a systematic screening strategy be proposed?
- For which population?
  - The whole population (general population screening proposal)?
  - Populations at risk (targeted screening)?
- How often should screening be proposed for each population studied?
  - A single screening test?
  - A screening test repeated every 10 years, 5 years, 3 years or every year?

The following strategies were compared:

- Current screening strategy: screening strategy based on individual voluntary testing on the initiative of all persons wanting to know their HIV serostatus either after exposure to a risk or not.
- Systematic screening for persons aged from 18 to 69 years :
  - Once;
  - every 10 years;
  - every 5 years;
  - every 3 years;
  - every year.

These strategies were studied in different high risk populations (MSM, heterosexuals, IDU), in French Guiana but also in the general population.
The model compared the total costs generated by the deployment of new screening strategies (total direct cost) with their medical effectiveness (number of quality-adjusted life years gained). Calculations were performed to compare costs and effectiveness with the previous strategy.
Modelling results were interpreted taking into consideration different efficiency thresholds (threshold proposed by WHO and cost-effectiveness ratios of different public health interventions).

2.2.4 Conduct of the studies

The results of the systematic review of the literature and modelling studies were discussed by a multidisciplinary working group, including representatives of patient associations. This working group met four times between November 2008 and July 2009. In addition, a sub-group was set up to make proposals for counselling, from the review of the literature made by HAS project leaders. These proposals were discussed by the working group.
The evidence review and guidelines drafted after discussions by the working group were then submitted to a multidisciplinary peer-review panel which gave its opinion on the quality and form of the rationale and the relevance and applicability of the guidelines.

3 French HIV screening system and strategies: possible future developments

After analysing the current epidemiological situation, the literature review and modelling studies and after discussions among the working group, possible future developments in the screening strategies and improvements in the current system were defined.

3.1 New strategies to be implemented and evaluated: proposal for routine HIV screening and targeted HIV screening

As late HIV testing is still common in populations not traditionally considered to be “at risk”, and because the continuing epidemic of HIV infection affects more particularly population groups and regions, a strategy should be developed providing an improved knowledge of the serostatus of the general population. This screening strategy has two main arms:

- proposed routine testing of the general population not necessarily exposed to a risk of contamination by HIV, which must be evaluated after 5 years for a quantitative;
- evaluation of the extension of screening and its consequences on the reduction in late testing;
- In parallel the maintenance and stepping up of regular targeted screening for high risk populations.

3.1.1 General population screening proposal

► Objectives

The primary objective of such an approach is to improve early detection of HIV infection and ensure timely access to medical care. Secondarily, it may also help promote the idea that the improvement in knowledge of HIV serostatus by the general population may provide large benefits both at individual and community level.

► Populations

By definition, this proposal is addressed to the whole of the general population or a subset of this population (as in case of universal antenatal screening), with no distinction according to the evaluation of the risk of exposure to or infection by HIV. In the present case, the target population corresponds to the general population aged from 15 to 70 years.

► Procedures and players

The principle of the initial phase of this approach is the mobilisation of all players involved in screening for a predefined time period followed by an evaluation of the extent to which the objective has been reached (reduction in late testing).
The operational execution of such a strategy requires the active participation of all health professionals and structures involved in dispensing primary care, and above all general practitioners.
General practitioners are the main relays for this strategy of proposing HIV testing to the whole population. The promotion of this strategy involves reaffirming the tasks of these healthcare professionals in the screening and prevention of HIV infection. The desired mobilisation of all these players must be supported by communication and provision of specific information for general practitioners (use of different media, development of different information supports and various dialogues, etc). The purpose is to promote the message that an improved therapeutic efficacy in the management of HIV infection involves early intervention after proposing routine screening to the general population. This support is all the more necessary as the success of proposing general population screening depends on the active participation of general practitioners and other players of the primary care system.
Other structures or healthcare professionals should also take part in the implementation of this broader screening strategy:

- Medical gynaecologists and gynaecologist-obstetricians;
- University medicine departments;
- Family planning and education centres;
- Infant and maternal welfare centres;
- Primary health care access systems (permanent health care centres (PASS), general medicine clinics in community health centres for socioeconomically deprived persons, migrant health clinics, etc.);
- And at the end of on-going experiments in France, if they show a sufficient public health benefit, hospital emergency departments.

In addition a screening test could also be more widely proposed to the general population requiring hospital care for instance during preoperative management. Under these circumstances too, such a proposal should be made explicitly and the positive or negative test result must be given to the patient by the prescriber or a health professional from the same practice team.

The mobilisation of primary care health care providers to implement the proposed general population screening may be usefully supported by a parallel communication campaign, reaching the general population in order to inform it about these changes in screening

strategy and their goals. This campaign must stress that everyone should know their HIV serostatus.

This general population screening proposal must be mainly based on the techniques recommended by HAS during the first section of present guidelines, published in October 2008 (combined Elisa test). The use of rapid screening tests is justified at individual level in the case of an emergency and community level within the framework of a specific organisation (e.g.: Emergency Department, associative actions on specific patient populations, etc.).

It should be possible to determine the impact of this strategy by measuring the results after a five-year period. This will require the setting up of a system to evaluate the program and the results in terms of a reduction in late diagnosis, effects on high-risk practices and improvement in morbidity and mortality. A specific work must be initiated beforehand to define the components of this evaluation system.

In addition, the consequences of such a strategy, and in particular the increase in the number of persons testing positive for HIV must be anticipated so that the healthcare system, in particular at hospital level, is able to guarantee access to appropriate medical care.

3.1.2 Regular, targeted screening

In parallel with this proposal for general population screening, the systematic offer of regular targeted screening for specific patient populations and circumstances must be developed and integrated in a long-term strategy.

► Populations concerned

Some populations should be periodically offered an HIV screening test:

- Men who have sex with men (MSM);
- Heterosexuals who have had more than one sexual partner during the last 12 months;
- Populations of the French departments of America;
- Injectable drug users (IDU);
- People originating for regions of high prevalence, in particular sub-Saharan Africa and the Caribbean;
- Persons engaged in prostitution;
- Persons whose sexual partners are infected by HIV.

Screening frequencies were defined from the results of modelling studies or their transposition to the following target populations:

- Every year for MSM with multiple partners;
- Every year for IDU;
- Every year for persons with multiple partners originating from sub-Saharan Africa and the Caribbean.

Apart from these three cases, no precise guideline about screening frequency could be made as the necessary data for modelling studies were lacking.

Structures and systems, complementary to the players implementing the proposed general population screening program, constitute the relays of this strategy:

- CDAG/CIDDIST;
- Drug addiction prevention, treatment and counselling centres;
- Some associative structures, depending on the results of ongoing projects.

► **According to circumstances**

A screening test for HIV infection must be systematically proposed, whatever the population, in a number of specific circumstances:

- Suspected or confirmed STI or hepatitis B or C;
- Suspected or confirmed tuberculosis;
- Planned pregnancy;
- Abortion;
- First prescription of a contraceptive;
- Rape;
- During imprisonment.

► **The case of French Guiana**

Because of the epidemiological characteristics of HIV infection in French Guiana which place this department in a generalised epidemic situation, HAS recommends the implementation of voluntarist screening strategies based on:

- Proposal of the screening test for HIV infection;
- To the whole of the general population;
- Repeated every year;
- Within the scope of primary healthcare or hospital care.

Specific structures using RSTs must be developed in the short term, outside the framework of biomedical research, to reach groups without access to conventional systems. These structures, coordinated by the COREVIH, must be developed in co-operation with the institutional and associative players and based in particular on the use of outreach systems.
Lastly, screening for HIV infection must be integrated in a more global approach including all STI and hepatitis B and C.

3.2 Current strategies to be improved and consolidated in a renovated system

3.2.1 Voluntary risk-based screening

Voluntary screening is one of the mainstays of the current screening strategy for HIV infection in France, and in most developed countries. As pointed out by the WHO in May 2007, the development of this screening strategy must be encouraged and facilitated. After discussions within the working group and on basis of the literature review, several potential avenues of improvement may be attempted concerning dedicated and undedicated systems.

► **Development of the role of non-dedicated structures**

Role of general practitioners

Several possible pathways for improvement may be examined that further reinforce the role of general practitioners in screening for HIV infection, in particular for the most highly exposed populations:

- Summary of the major role of these players in the system;
- Extension of the use of RSTs to GP surgeries in order to facilitate access to screening of populations making insufficient use of the current system with respect to their exposure to risk and improvement of access to screening results under the conditions established during the first section of present guidelines and subject to the setting up of an exhaustive prospective follow-up of the results and performances of these tests.

The place of clinical laboratories

Practice of voluntary screening could be extended by allowing medical biology analysis laboratories to directly perform screening tests without a prescription.

Clinical laboratories are the principal healthcare structures involved in screening for HIV infection in France.
In addition, according to the results of the KABP general population survey in 2004, 7.3% of the persons questioned reported that they had undergone a screening test in this type of structure without a medical prescription. There therefore seems to be a demand for direct access to screening by laboratories performing these tests though this is difficult to quantify and characterize.

It is therefore appropriate, under these specific conditions, to authorise medical biology analysis laboratories to perform HIV tests without a medical prescription, subject to the respect of conditions for disclosing the result of these tests. These conditions were summarised in the first section of present public health guidelines on screening for HIV infection, published in October 2008.
For tests performed without a prescription at the patient's request, HAS considers that it is the laboratory specialist's responsibility to inform the patient. The result must be disclosed during an interview in which the laboratory pathologist advises the patient to contact his regular doctor. In the case of positive results, if the patient does not have a primary care physician, laboratory pathologists should propose counselling so that preventive and therapeutic management may be proposed without delay. In particular, the patient may be referred to a primary care-hospital network or any centre set up by the COREVIH.

A combined Elisa test must always be used for this screening according to the HAS guidelines.

► **Improve the role of dedicated structures**

Necessary changes to CDAG/CIDDIST

The CDAG (free, anonymous screening centres) have always had a specific and emblematic role in screening for HIV infection and must retain an essential place within the framework of voluntary screening. The reaffirmation and the necessary restoration of their role involves fusion of these structures with CIDDIST, the refocusing of their activity on their initial tasks and increasing their means.

The changes heralded by the law of 13 August, 2004 concerning privacy, local responsibilities and recentralisation of skills to fight STI in order to improve the consistency of actions implemented against HIV/AIDS should be continued until completion. This should result in an integrated organisation with a single structure, a single name, a single means of funding, a single activity assessment and the broad task of prevention and screening for HIV, hepatitis and STI.

Initially, the main task of the CDAG was to provide access to screening and prevention to persons vulnerable to risks throughout France. In particular, five priority objectives were defined by DGS/DH/DSS circular n°98-423 of 9 July 1 998:

- Provide early access to care after exposure to a risk;
- Make the system visible to all;
- Facilitate access to screening for socioeconomically deprived persons and those vulnerable to risks;
- Reinforce prevention;
- Reinforce the link between screening and care.

In the current context of the epidemic of HIV infection in France, these tasks are still extremely relevant. They must therefore be effectively implemented by the CDAG. Some of these tasks may be the subject of complementary developments in particular concerning follow-up and management of HIV infection: prescription of post-exposure prophylaxis including in extra-hospital CDAG/CIDDIST, according to local conditions, conduct of the initial assessment in the case of diagnosis of HIV infection in collaboration with hospital departments. Likewise, decentralised screening actions in associative centres may be developed for specific population groups.
It is also important to reaffirm the reference structure role of CDAG/CIDDIST concerning sexual health.

The effective implementation of these tasks involves developing the means of the CDAG/CIDDIST. The respect of the contract specifications of these structures involves improving their professionalisation, drafting a good practice guide, development of training about structuring individually tailored prevention strategies or the creation of a national coordination for CDAG/CIDDIST.
In addition, although anonymity is one of the principles of operation of the CDAG and desired by users, it may constitute an obstacle for continued care. It therefore seems appropriate to make it possible to lift anonymity, with the subject's formal agreement, in order to assist continued management, in particular after diagnosis of an HIV infection, to facilitate implementation of treatment in the case of STI and to allow the management of exposure accidents in these structures.

The development of the role of associative structures
Associative structures may be recognized to play a new role in the HIV screening system. According to the model of experience gained in the USA and some European countries, this role is to extend the screening offer to the most exposed populations, in order to better meet their needs. Associative structures should not be considered to be in competition with existing dedicated systems but rather as specific relays to reach populations not using or insufficiently using current testing sites and integrate this screening in the *continuum* of associative preventive actions.

Within the scope of the first section of the present public health guidelines, HAS recognised the role of associative structures, and considered in particular that RSTs could be used in alternative decentralised structures closer to the target population. It also recommended the implementation of projects based on the use of RSTs by these structures in order to evaluate the feasibility and benefits of these new screening models.

3.2.2 Universal prenatal screening

Since French law n°93-121 of 27 January 1993 concer ning sundry social measures, the systematic screening for HIV infection has been proposed to pregnant women during the first prenatal appointment after prior collection of their consent.
The relevance and acceptability of this strategy are now firmly established in France and in most developed countries. Moreover, because of the success of this screening model, suggestions were made in the early 2000s, in particular by the CDC in the United States, about the need to extend these broad screening strategies to the general population.

The most recent French guidelines on this subject also recommend:

- The proposal of serological testing during the visit at 6 months of pregnancy to seronegative women exposed to a viral risk, in particular if the partner is HIV-seropositive or has an unknown status;
- The proposal of an HIV screening test to all future fathers.

This latter point was the object of a regulation: the HIV screening test is now included in the examination at 4-months of the future father envisaged by National Health Insurance within the scope of antenatal care. However, according to the members of the working group, such a provision is only rarely implemented at the present time.

In addition, the review of the literature, based on a limited number of studies with a low level of evidence, suggests that the implementation of a universal *opt-out* screening strategy during pregnancy may improve screening acceptance and screening rates.
Such a strategy may therefore be promoted provided that pregnant women are clearly informed that the test will be performed unless they decline testing and that they are provided with a minimum amount of information before screening.

HIV testing during pregnancy should therefore be proposed:

- During the 1st antenatal appointment for all pregnant woman according to the *opt-out* principle, within the scope of the laboratory tests that are systematically performed;
- During the 3rd trimester of pregnancy to seronegative women exposed to a risk (IDU, sex workers, sexual partners of HIV-infected persons, new or more than one sexual partner during pregnancy);
- To partners and future fathers before birth.

The proposal of a screening test to partners and future fathers may be facilitated by proposing screening to the whole population.

3.2.3 Early detection of primary HIV infection

Although the case of early detection of clinical signs suggesting chronic HIV infection or AIDS were excluded from the scope of the present guidelines, it was considered relevant to point out situations close to a diagnostic procedure when these form part of secondary prevention or reduce secondary transmission.
It is important to underline the need to perform an urgent combined Elisa test in any patient with acute infection compatible with primary HIV infection. Both patients and healthcare professionals should be reminded of the clinical signs of primary HIV infection.

For the same reasons, the repetition of the screening test should be encouraged in patients at persistent risk of HIV infection.

Clinical signs suggesting primary HIV infection in persons at risk

According to the Yeni expert report published in 2008, primary HIV infection should be suspected in subjects presenting clinical signs compatible with a persistent acute viral syndrome associated with polyadenopathy, mucocutaneous and/or neurological manifestations:

- Fever
- Weight loss
- Maculopapular rash
- Oral and/or genital ulcers
- Multiple lymph node enlargement
- Muscle and joint pain
- Pharyngitis
- Gastrointestinal disorders
- Headaches
- Other neurological signs

3.3 Place of counselling

The purpose of counselling, defined as individually-tailored advice and information, is to help persons make decisions, resolve problems and cope with crises obliging them to make a series of changes for which they do not necessarily feel prepared. In the field of health and screening for HIV infection, counselling is given to single individuals or groups. It must be provided by professionals or peers who have received basic training in conducting interviews and on the health topic about which the user or patient must acquire knowledge or specific skills.
Since 1987, counselling has become an integral part of the procedure of screening for HIV infection. As initially there were no effective therapeutic strategies, patients proposed HIV testing had to be given psychological support in order to reduce the traumatic impact of the possible announcement of seropositivity. Since 1996 and the development of HAART and the reduction in HIV-related mortality, counselling strategies have changed and the objective is now to encourage testing by proposing effective treatment. Gradually, therefore, counselling has lost its initial role of psychological support and this has been replaced by advice about primary prevention as it was feared that avoiding HIV infection would seem less important now that treatments exist.
Discussions initiated in the early 2000s about changes to the HIV screening model also concerned counselling, as some authors considered that pretest counselling, often presented as mandatory, was an obstacle to screening.
The proposals developed below about the role of counselling within the scope of screening strategies for HIV infection in France are derived from the results of the literature review and the reflections of a specific sub-group (presented in appendix 2) and were discussed by the working group.

3.3.1 Relevance of counselling during HIV screening

A priori, counselling forms a crucial part of screening as this include elements requiring a form of support, accompaniment or help in making changes, in particular, when these concern sexual practices or the adoption of risk-reduction behaviours. Counselling has been recommended since 1987 and is defined as a structured offer to be proposed to all persons wishing to have a screening test. Counselling however should not constitute an obstacle to early access to screening, the importance of which for the general public has become particularly clear since effective therapies have become available. This is particularly true as the value of counselling is diminished by making it mandatory or when it is practiced by professionals or individuals with little training.

3.3.2 Feasibility of counselling in the screening program

Experts and practitioners agree that in France the postulates and values of counselling as defined above have been integrated in the support systems and associations working for seropositive subjects but little has been done for seronegative individuals or prevention. Counselling is rarely practised during primary prevention as it requires specific training and an operational know-how about theories of behaviour change, an acceptance of concepts such as the reduction in sexual risks and, in the case of injectable drug use, a recognition of traumatic environments that hinder prevention (sexual abuse, poor self-esteem, reactional sexual addiction, homophobia, economic dependence, violence between couples).

3.3.3 Counselling and new screening strategies

The practice of counselling must therefore be adapted to the screening procedures used and the setting of the healthcare offer.
Within the scope of the recommended routine screening strategy, counselling may be limited to the provision of appropriate information in order to obtain informed consent and an assessment of the person's capacity to receive the test result. The aim here is for general practitioners and other healthcare professionals in different healthcare structures to encourage HIV testing. This offer must be guided by the existence of a strong therapeutic promise about treatment of the HIV infection and a presentation of the expected individual benefits.
Outside this framework, proposed counselling must be appropriate to the different settings of the screening offer: screening test offered by trained professionals in the case of more or less repeated exposure to a risk, offer or access to rapid screening in associative structures, etc.
The objectives of the present public health guidelines do not include a definition of the contents of counselling in different settings or population groups. A specific work must therefore be performed in order to devise national specifications for counselling as well as specific counselling guides for each type of screening offer, taking into account the wide range of populations, sites and associative, community and professional cultures concerned.

Conclusions and guidelines

PREFACE: These conclusions comprise the second part of the public health guidelines on screening for HIV infection drafted by the Haute Autorité de Santé at the request of the General Directorate of Health. They concern the HIV screening system and strategies. The first section, published in October 2008, discussed the question of the procedures for performing screening tests for HIV infection (cf. appendix 3). Although these guidelines were divided into two sections in particular to address specific expectations concerning rapid screening tests, the technological discussion about screening tests and the procedures for performing them should not be dissociated from the more general strategic framework of screening for HIV infection. The HAS therefore underlines that these two sections comprise a global response to the challenge of screening for HIV infection in France.

The present guidelines concern all HIV screening strategies, in persons aged 15 years or more, except for the mandatory screening of blood donations and in organ or tissue donors. Patients presenting clinical symptoms suggesting an established HIV infection or AIDS are also excluded from the scope of these guidelines.

The guidelines are based on a critical review of the literature and health economic modelling studies performed in partnership with InVS, CRESGE and INSERM under the direction of Prof. Yazdanpanah and were drafted in agreement with the working group.

Main messages

Because of the persistence of late testing of HIV infection in particular by specific population groups that do not consider themselves to be “at risk”, and because the epidemic still affects population groups and regions in particular, the HAS recommends a two-part screening strategy:

- The objective of the first part is to improve early detection and to reduce late screening for HIV infection. It consists in proposing HIV screening to the whole population aged from 15 to 70 years including subjects with no particular characteristics and not exposed to any specific risk. It is based on the active mobilisation of general practitioners and other health providers. The results and impact of this strategy on the reduction in the number of late testers must be assessed after a first 5-year period. This guideline also aims to modify society’s image of HIV screening by promoting the idea that an improvement in a population’s awareness of its HIV serostatus may provide major benefits both at individual and community level.
- The other part takes into account the heterogeneity of the epidemic of HIV infection in France and the persistence of population groups that are more specifically affected. It involves the proposal of periodical targeted HIV screening in populations (men who have sex with men (MSM), heterosexuals who have had more than one sexual partner during the last 12 months, injectable drug users (IDU), people originating from regions with a high prevalence, persons engaged in prostitution, persons whose sexual partners are HIV-seropositive) and in circumstances.
- Concerning French Guiana, the HAS underlines the particular epidemiological characteristics of HIV infection which place this department in a generalised epidemic situation, and insists on the need to implement voluntarist screening strategies based on the regular proposal of the screening test to the whole population.

In addition, the HAS considers that voluntary screening should be encouraged and facilitated. The practice of voluntary screening must therefore remain one of the cornerstones of the screening system based in particular on general practitioners and

CDAG/CIDDIST. In this respect and on basis of the literature review and after discussions by the working group, several potential avenues of improvement were proposed concerning dedicated and non-dedicated systems.

Lastly, the HAS recommends that the general population screening proposal is accompanied by the provision of appropriate information in order to obtain informed consent and an assessment of a person's capacity to receive the test result. Outside this framework, appropriate counselling must be offered in the different settings of the screening offer.

General principles

1. Although these guidelines exclusively discuss the question of HIV screening strategies, such screening should not be designed as an isolated public health intervention and must be integrated in a global preventive approach including all sexually transmissible infections and hepatitis B and C according to the population at risk.

2. Any patient newly diagnosed with an HIV infection must be referred for appropriate medical care with psychological and social support involving all the health providers concerned. The relations between screening structures and specialised hospital departments and general practitioners and private specialists caring for HIV-positive patients must be reinforced in order to facilitate rapid clinical evaluation.

3. The recommended changes in HIV screening strategies, whether these are the promotion of new strategies or the improvement in current strategies based on individual initiatives, do not compromise principles on which the HIV infection screening system was built and which must be preserved:

    - The persons' rights (respect of confidentiality, anonymity, appropriate information and informed consent);
    - Free access to a varied screening offer and the relation with appropriate management;
    - The practice of voluntary screening.

4. Counselling strategies must be appropriate to the setting in which the screening offer is proposed. Health providers and counsellors must propose help with prevention adapted to a person's needs (in particular in the case of repeated exposure to a risk, after a specific request from the consulting person or when the result of the screening test is positive).

New screening strategies to be implemented and evaluated

5. In order to improve early detection and reduce late screening for HIV infection, HAS recommends that a screening test is proposed to the whole general population aged from 15 to 70 years including persons with no specific characteristics or who have not been *a priori* exposed to a risk of infection.
   The implementation of this general population screening proposal requires the mobilisation of all health providers and in particular all health professionals and structures involved in dispensing primary care.
   General practitioners are the main relays for this strategy of proposing the screening test to the whole population.
   Other healthcare structures or professionals are also invited to take part in the implementation of this screening strategy:
    - Medical gynaecologists and gynaecologist-obstetricians;

- University medicine departments;
- Family planning and education centres;
- Infant and maternal welfare centres;
- Primary health care structures (permanent health care centres (PASS), general medicine clinics in community health centres for socioeconomically deprived persons, migrant health units, etc.);
- and, if on-going experiments in France show a sufficient public health benefit, hospital emergency departments.

In addition, a screening test may also be more widely proposed to the general population when receiving hospital care for instance during preoperative management. Under these circumstances as well, the proposal should be explained and the positive or negative test result should be given to the patient by the prescriber or a health professional from the same practice team.

The mobilisation of primary care providers around this proposal should be supported by specific information and communication for general practitioners (fact sheet explaining the importance of this testing strategy, use of different media, development of information supports and dialogues, etc) and the general public (information in pharmacies, waiting rooms, etc) providing information about the importance of screening and the increased role conferred on general practitioners.

Such a screening strategy must be mainly based on the techniques recommended by HAS in the first section of the present guidelines, published in October 2008 (combined Elisa test). The use of rapid screening tests is justified at individual level within a medicalised structure in the case of an emergency and community level within a specific organisational framework (e.g. : Emergency Departments, associative actions with specific patient groups, etc.).

The results and impact of this proposal will be measured after a five-year period. This will therefore require the setting up of a system to evaluate the screening system and its results in terms of a reduction in late diagnosis, the effects on high-risk practices and improvement in morbidity and mortality. A specific work must be initiated beforehand in order to define the components of this evaluation system.

6. In parallel with this proposal for extending screening to the general population, the systematic offer of regular targeted screening for specific patient populations and circumstances must be developed and integrated in a long-term strategy.

Populations concerned

Some populations should be offered periodic HIV screening tests:

- Men who have sex with men (MSM);
- Heterosexuals who have had more than one sexual partner during past 12 months ;
- Populations of the French departments of America;
- Injectable drug users (IDU);
- People originating from regions of high prevalence, in particular Sub-Saharan Africa and the Caribbean;
- Persons engaged in prostitution;
- Persons whose sexual partners are infected by HIV.

Screening frequencies were defined from the results of modelling studies or their transposition to the following target populations:

- Every year for MSM with multiple partners;
- Every year for IDU;

- Every year for persons with multiple partners originating from sub-Saharan Africa and the Caribbean.

The working group cannot define more precise guidelines for screening frequencies outside these three cases.

Structures and systems, complementary to players involved in the implementation of the universal screening strategy, constitute the relays of this strategy:

- CDAG/CIDDIST;
- Drug addiction prevention, care and counselling centres;
- Some associative structures, depending on the results of ongoing projects.

According to circumstances
A screening test for HIV infection must be systematically proposed, whatever the population, in a number of specific circumstances:

- Suspected or confirmed STI or hepatitis B or C;
- Suspected or confirmed tuberculosis;
- Planned pregnancy;
- Abortion;
- First prescription of a contraceptive;
- Rape;
- During imprisonment.

7. Because of the epidemiological characteristics of HIV infection in French Guiana placing this department in a generalised epidemic situation, HAS recommends the implementation of voluntarist screening strategies based on the proposal of HIV screening to the whole general population and repeated testing every year by primary care clinics and when patients receive hospital care.
   Specific structures using rapid screening tests (RSTs) must be developed in the short term, outside the framework of biomedical research, to reach groups without access to conventional systems. These structures, coordinated by the COREVIH, must be developed in co-operation with the institutional and associative players and based in particular on the use of outreach structures.

<u>Current strategies to be improved and consolidated in a renovated system</u>

8. Voluntary screening must be encouraged and facilitated.

   In this setting HAS points out that general practitioners are the first point of contact for all subjects exposed to a risk of contamination. The use of RSTs in GP surgeries may be envisaged not only to facilitate access to screening of populations whose use of the existing system, for various reasons, is insufficient in relation to their exposure to risk, but also to improve access to screening results. In this setting, the conditions for using RSTs defined in the first part of present guidelines must be respected (and in particular the setting up of a quality assurance system) and an exhaustive prospective follow-up of the results and performances of these tests must be conducted.

   The HAS considers that CDAG and CIDDIST must continue to play an important role in the voluntary screening program. These structures must be renovated by their fusion at organisational level, the respect of their specifications and reinforcement of their means.
   The CDAG and CIDDIST must be integrated in a unique structure with a single name, a single mode of financing, a single activity report and the broad task of prevention and screening for HIV, hepatitis and STI.

The tasks initially assigned to the CDAG are still completely relevant:

- Facilitate access by proximity, suitable opening times, and provision of anonymous, free, walk-in care (without an appointment, or in some cases a mixed system with or without an appointment);
- Permit early management after exposure to a risk;
- Make the system visible to all;
- Facilitate access to screening for the socioeconomically deprived and those vulnerable to risks;
- Reinforce prevention;
- Reinforce the link between screening and treatment.

They should be effectively implemented so that these structures become the reference centres for sexual health. Some of these tasks may be extended to include, in particular, the follow-up and management of HIV infection: prescription of post-exposure prophylaxis including in CDAG/CIDDISTs outside the hospital, depending on local conditions; conduct of the initial assessment in the case of diagnosis of an HIV infection in collaboration with hospital departments. Likewise, decentralised screening actions at associative centres may be developed for specific population groups.
The effective implementation of these tasks involves developing the means of the CDAG/CIDDIST. The respect of the contract specifications of these structures involves improving their level of professionalisation, the drafting of a good practice guide, the development of counselling training or the creation of a national coordination of CDAG/CIDDIST.
Finally, the lifting of anonymity may be envisaged, after obtaining the agreement of the consulting person and according to a formal procedure, in order to improve continuity of care, in particular in the case of diagnosis of an HIV infection, to facilitate implementation of treatment in the case of STIs and to allow management of exposure accidents in these structures.

The HAS also recommends that it is made possible to perform screening tests in clinical laboratories, without a prescription, provided that the conditions for disclosing the result of the screening test summarised by HAS in October 2008 are respected. The combined Elisa test should be used for this test according to the algorithm developed in the first section of the present public health guidelines on screening for HIV infection.

The implementation by associative structures of specific programmes integrating screening within the continuum of preventive actions must be supported in order to reach populations without sufficient access to screening or with specific needs for a preventive approach according to the results of on-going projects. In this setting, the conditions of use of RSTs established in the first part of the present guidelines must be respected (and in particular the setting up of a quality assurance system) and an exhaustive prospective follow-up of the results and performances of these tests must be conducted.

9. The HAS points out that it is important for all healthcare professionals to propose a screening test for HIV infection to all pregnant women during the 1st antenatal appointment. This proposal may be made within the scope of the laboratory tests that are systematically performed provided that general information is provided beforehand and that women are told off their right to opt out.

   The screening test must again be proposed during the 3rd trimester of pregnancy to seronegative women exposed to a risk (IDU, women engaged in prostitution, sexual partners of HIV-infected persons, new or more than one sexual partner during pregnancy).

The HAS also underlines the importance of proposing a screening test to partners and future fathers before the birth.

10. The HAS recommends that a combined Elisa test is rapidly proposed to all persons presenting with acute infection compatible with primary HIV infection. Both patients and health professionals should be reminded of the clinical signs of primary HIV infection.

    For the same reasons, HIV testing should be periodically repeated in persons persistently exposed to a risk of HIV infection.

11. General population screening may be proposed to subjects outside risk groups provided that they receive appropriate information in order to obtain their informed consent and an assessment is made of their capacity to receive the test result.

    Outside this framework, HAS recommends the proposal of counselling appropriate to the different settings of the screening offer. For this purpose, a specific work must be performed to decide on the contents of this counselling according to the setting and population concerned.

Prospects and future research

Several major needs for information and additional focus areas for complementary studies have been identified and must be taken into account in the medium term to improve the screening system and strategies in France:

- Evaluation of the use of partner notification strategies within the scope of the screening for HIV infection.
- Development of national specifications for counselling including the following items in particular: competences to be acquired by providers, topics to be discussed during the interview, ethical principles of counselling within the scope of the use of rapid screening tests, list of available resources (players and structures) in order to continue counselling once it has been initiated.
- Drafting of specific counselling guides tailored to each context of the screening offer, and taking into account the wide range of audiences, sites and associative, community and professional cultures.
- These guides should be used as a practical aid to counselling and follow-up and as a reference tool for training activities.

Appendix 1. Composition of the follow-up committee for the modelling studies

Principal investigator: Yazdan Yazdanpanah
Co-investigators:

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- ***CRESGE, Lille***: Benoît Dervaux, Sylvie Deuffic Burban, Cécile Charlois, Karen Champenois
- ***INSERM, Paris***: Dominique Costagliola
- ***Partners AIDS Research Centre, Massachusetts General Hospital, Harvard Medical School***: Kenneth Freedberg, Rochelle Walensky, Elena Losina, Caroline Sloan.
- ***Yale School of Public Health***: David Paltiel

Sponsor: HAS
Working group: Cécile Charlois, Dominique Costagliola, Benoît Dervaux, Kenneth Freedberg, Stéphane Le Vu, David Paltiel, Anne-Isabelle Poullié, Catherine Rumeau-Pichon, Caroline Semaille, Olivier Scemama, Caroline Sloan, Rochelle Walensky, Yazdan Yazdanpanah

Appendix 2. Reflections of the working sub-group on counselling

Sub-group composition:

- Dr Éric BILLAUD, Infectologist, Nantes
- Dr Philippe DHOTTE, General practitioner, CIDAG du Figuier, Paris
- Mr. Jean-Marie Le GALL, Community Leader (AIDES), Pantin
- Dr Michel OHAYON, General practitioner *Sida Info Service*, Paris
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- Mrs Catherine TOURETTE-TURGIS, Psychologist, Paris

Counselling is defined as individually-tailored advice and information provided in order to help persons make decisions, resolve problems and cope with crises obliging them to make a series of changes for which they do not necessarily feel prepared. Its objective is to help persons mobilise their own resources while taking into account the environment which may act as a lever or a hindrance to change. In the field of health and screening for HIV infection, counselling is given to single individuals or groups. It must be provided by professionals or peers who have received a minimum of training in conducting interviews and about the health topic for which the user or patient must acquire knowledge or specific skills.

Importance of counselling during screening for HIV infection

Counselling is a crucial component of a screening program as this includes elements requiring a form of support, accompaniment or help in making changes, in particular when these have complex dimensions such as modifications of sexual practices or adoption of risk-reduction behaviours. Counselling has been recommended since 1987 and is defined as a structured offer to be proposed to all persons wishing to undergo a screening test. Counselling however should not constitute an obstacle to early access to screening, the importance of which for the general public has become particularly clear now that effective therapies are available. This is particularly true as counselling may no longer be considered relevant if it is mandatory or if it is practiced by professionals or individuals with little training.

Feasibility of counselling in a screening program

Experts and practitioners agree that in France the postulates and values of counselling as defined above have been integrated in the support systems in associations working for seropositive subjects but little has been done for seronegative individuals or prevention. Counselling is rarely practised during primary prevention as it requires specific training and an operational mastery of theories of behaviour change, an acceptance of concepts such as the reduction in sexual risks and, in the case of injectable drug use, a recognition of traumatic environments that hinder prevention (sexual abuse, poor self-esteem, reactional sexual addiction, homophobia, economic dependence, violence between couples).

Counselling and new screening offers

The rapid screening offer represents a valid opportunity for individual and community health provided the HAS guidelines published in October 2008 are respected.

It is therefore important to take it into account and accompany it by access to support during prevention after making a rapid diagnosis of the needs and wishes expressed by individuals or groups who will be the recipients during routine screening or users of voluntary testing.

Counselling must therefore be adjusted to each of the following settings: routine offer by untrained professionals, offer by trained professionals, an offer or access to rapid screening in associations or a public health offer for the purposes of general population screening.
For rapid screening it is also important to define the essential points to be discussed in order to provide basic facilitating and non-constraining support integrating both the interest of the requesting individual or beneficiary and the possibilities of health professionals to propose rapid screening to their patients.
For persons, groups or communities exposed by their history, cultural origins, sexual orientation, or living conditions to a deficiency of wellbeing, the objective is not only to provide access to rapid screening but also to open spaces for psychological support led by persons, associations and legitimate peers trained in community counselling techniques privileging support, risk-reduction behaviours, a fulfilling sex life and self-esteem.

Counselling strategies according to setting

The value of counselling lies in its capacity to adjust to different settings. Health professionals and staff may play a counselling role according to their level or training and also their scope of practice. Counselling requires a context that facilitates listening and allows time to develop a type of relation in which one person accompanies another by helping him/her to formulate, clarify and carry out a project without imposing it. The objectives of counselling are realistic and achievable in a defined space-time but are modulated by the setting or a triggering event (crisis counselling, diagnosis disclosure counselling, traumatic event, prevention counselling).

Routine screening offer by untrained professionals

Counselling provided when offering routine screening must comply with three criteria. The offer must be accompanied by the person's consent. It must not damage the relation of trust between the prescriber and patient required for continuation of care and should help maintain quality of life and quality of care.
This offer proposed by untrained professionals may proceed in three stages:

- An explanation of the proposal.
- Brief information about the existence of treatments and the importance of early management of HIV infection.
- The provision of more detailed supporting information about prevention in brochure form, for persons requesting it.

The offer must be guided by the existence of a strong therapeutic promise on treatment of HIV infection and the individual benefit of this treatment.

Routine screening offer by trained professionals

The routine offer of a rapid screening test by trained professionals may be accompanied by counselling about prevention, based on the interview guides proposed during training or other guides drafted by professionals already working in the field of screening. This counselling will aim firstly at establishing a climate of attention in order to help the person clarify her or her own demands and needs both with respect to screening but also for prevention. The goals are to help a person clarify his or her difficulties in adopting or maintaining prevention attitudes and behaviours. Where necessary, particular attention should be paid to referring the person to prevention resource centres by taking into account the major social, environmental, community and sexual factors explaining his/her difficulties in prevention and health in general.

- **Offer or access to rapid screening in associations**

When the members of an association have received training or when they already exercise a counselling role on the topic of prevention and sexuality, they are *de facto* providers of counselling defined as community counselling, which may take the form of support groups or peer-support co-counselling sessions. The value of these sessions is that they facilitate from the outset contact with other persons exposed to the same type of risks in a given environment, partly sharing common standards and memberships. Associations, provided that they adopt a counselling quality charter, are powerful levers of social recognition and provide an unconditionally positive viewpoint for active listening, change and support.
Counselling proposed by associations and practiced by volunteers trained in the multiple dimensions of prevention may address an objective requiring counselling work for several sessions for the benefit of persons who are or were exposed to a wide range of vulnerabilities or a deficiency of well-being hindering them from adopting prevention behaviours.

Appendix 3. HAS guidelines on HIV infection screening procedures (published in October 2008)

These guidelines were published by the HAS in October 2008 (HAS guidelines HIV screening part 1).

Guidelines on the methods for carrying out HIV infection screening and laboratory diagnosis

These guidelines relate to the methods used for HIV infection screening and laboratory diagnosis in adults and children aged over 18 months, with the exception of the screening of blood donations and of organ and tissue donors. They do not apply to rapid screening tests (RST), for which specific guidelines are described in detail in the following section.

General principles

The laboratory diagnosis of the HIV infection is based on a two-stage strategy: a **screening analysis** followed by a **confirmation analysis.** A positive screening analysis must always be supplemented by a confirmation analysis on the same sample. **An HIV infection can only be confirmed when the result of the confirmation analysis is positive and consistent results are obtained for two separate samples.**

The prescribing doctor is recommended to provide the laboratory specialist with the clinical information supporting[1] the diagnostic guidance.

Should one rather than two techniques be used for screening analysis?

Continuing to use two screening techniques on the same sample when carrying out a screening analysis for anti-HIV antibodies is no longer justified in 2008.

This change to current practice is based on an analysis of the performance achieved by the techniques currently available on the European market for HIV infection screening, as well as on a comparison of the performances of the strategies based on one or two screening techniques.

Choosing the screening analysis technique

Laboratory specialists performing the diagnosis of the HIV infection in the lab must use, as part of the screening analysis, a CE-marked combined ELISA test with a p24 Ag detection threshold at least equivalent to the minimum threshold required by the current European legislation applicable to p24 Ag detection tests[2].

[2] Especially age, a suspected primary infection, specific pathological situations (cases of co-infection, associated treatments etc.).
[3] In 2008 this threshold has been set at 50 pg/ml of HIV Ag.

If the screening analysis gives a negative result, this indicates the absence of any HIV infection, except if the patient is suspected of having been exposed to HIV within less than 6 weeks prior to this (see below).

Choosing the technique to use as part of the confirmation analysis and differentiation between HIV-1 and HIV-2 infections

The technique used as part of the confirmation analysis for an HIV-1 infection remains the Western blot (WB) or immunoblot (IB). The WB interpretation criteria for HIV are unchanged (criteria were defined according to the Anaes guidelines in 2000 and by the WHO) and are included in the appendix to this document.
It is recommended to differentiate between the infections caused by HIV-1 and HIV-2 respectively, due to pathogenic differences between the two types of virus, HIV-2's natural resistance to certain antiretroviral drugs and to the absence of off-the-shelf tests for quantifying the plasma HIV-2 RNA.
The confirmation analysis must therefore help ascertain whether an HIV infection is present or not, while also differentiating between the HIV-1 and HIV-2 infections.
If the result of the WB or IB is negative or indeterminate, in order to avoid missing a primary infection during the pre-seroconversion stage, a test needs to be carried to reveal the virus's components (detection of plasma viral RNA or p24 Ag with a detection threshold at least equivalent to that of the combined ELISA test used for the screening analysis, confirmed by a neutralisation test in the case of a positive result).

Confirmation of the HIV infection always requires the provision of consistent results from two separate samples.
If the screening analysis is positive, the confirmation analysis must be carried out on the initial sample. If the confirmation analysis is positive, a second sample must be taken and tested in order to eliminate any identity error. It is recommended to carry out a new screening analysis on this second sample (using the screening reagent used initially or a different one). A new confirmation analysis does not need to be carried out. Only a positive result with this second sample will be able to validate the result and confirm the diagnosis of an HIV infection.
Where problems arise in interpreting the results of these analyses, close consultation is recommended between the prescribing doctor and the laboratory specialist. Any atypical profile must be investigated using specific diagnostic techniques (specific serological tests for variants, viral isolation, genome detection tests etc.), especially if the clinical and/or epidemiological context is conducive to HIV exposure.

Issuing results

The test results must be issued in a confidential manner. With the patient's consent, this task is first entrusted to a doctor during a specific consultation, enabling him or her to provide information about preventing HIV infection and, if an infection has been diagnosed, to start managing and monitoring the patient.
If a test has been carried out without any prescription, at the patient's explicit request (i.e. outside the current regulatory framework), it is up to the actual laboratory specialist to inform the patient. The result must be issued during a discussion where the laboratory specialist advises the patient to contact his or her primary care physician. In the case of a positive result where there is no primary care physician involved, the laboratory specialist must offer support to the patient and can, in particular, direct the latter to a hospital-community network or any of the regional anti-HIV coordination centres (COREVIH).

These guidelines imply an upgrade to the current regulatory framework (1 October 2008). Furthermore, shifting from a strategy based on the use of two screening analysis techniques to a strategy based on the use of a single technique will result in modification of the Nomenclature of Procedures in Laboratory Medicines in terms of the procedure's description and rating.

Duration of serological follow-up in the case of suspected HIV exposure

Based on the performance of the techniques currently available on the European market, a negative result from the combined ELISA screening test 6 weeks after suspected HIV exposure will be considered as indicating that no HIV infection is present. In the case of post-exposure prophylaxis, the period remains 3 months after discontinuing treatment.

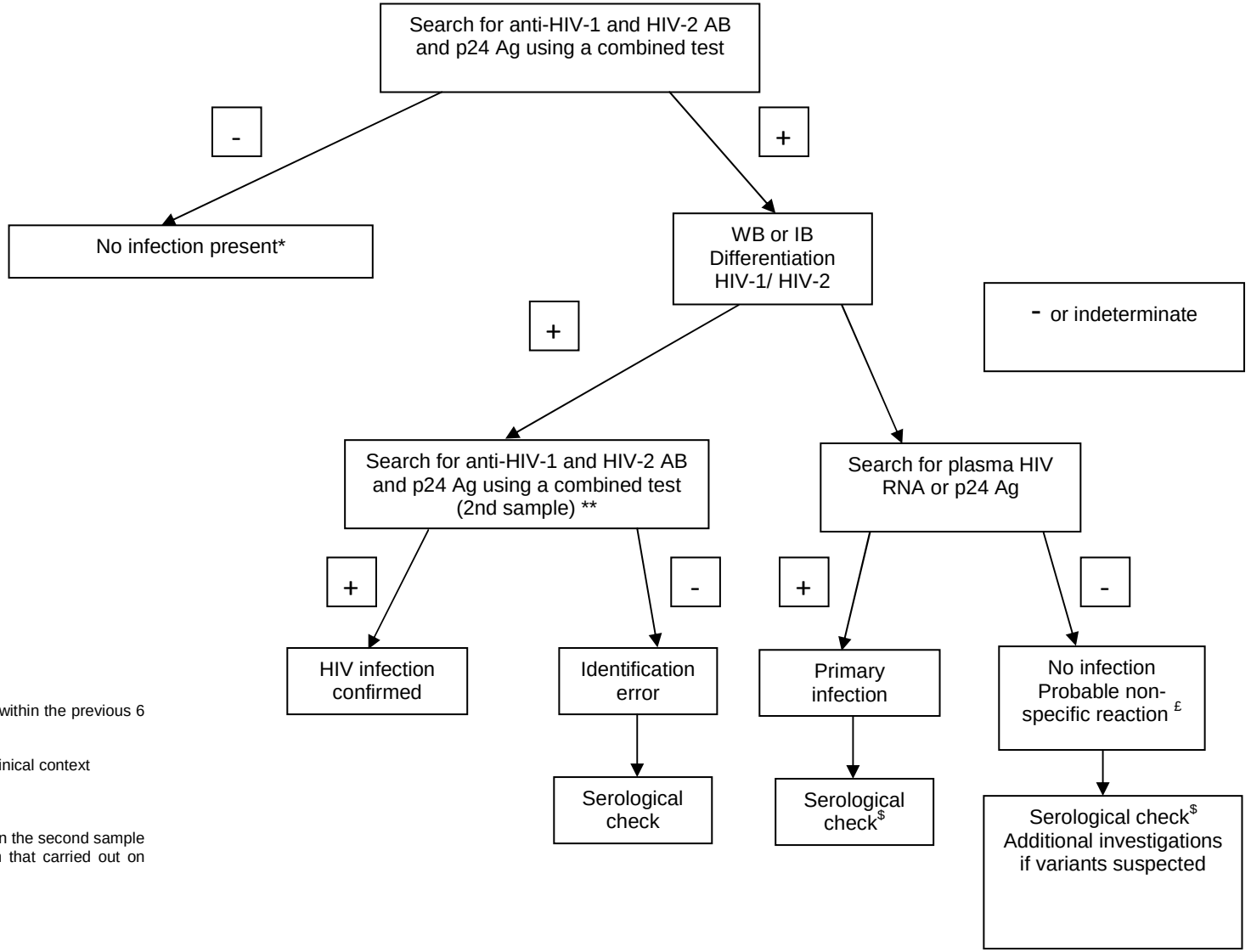
Screening and laboratory diagnosis strategy in the case of suspected HIV infection within less than 6 weeks and without any prophylactic treatment

An initial search for the HIV infection must be carried out in the exposed patient from the very first consultation, using the methods previously defined.
It will be repeated 6 weeks after the time of suspected HIV exposure.

Screening and laboratory diagnosis strategy in the case of suspected HIV infection and with prophylactic treatment

An initial search for the HIV infection must be carried out in the exposed patient from the very first consultation, using the methods previously defined. It will be repeated 1 month and 3 months after discontinuing the prophylactic treatment.
A negative result from the combined ELISA screening test 3 months after discontinuation of prophylactic treatment will be considered as indicating that no HIV infection is present.

SCREENING ALGORITHM
GENERAL CASE
ADULTS AND CHILDREN AGED OVER 18 MONTHS



* unless suspected HIV exposure within the previous 6 weeks
$ 1 to 2 weeks later
£ To be interpreted according to clinical context
+ : positive result
- : negative result
AB : antibody
** The combined test carried out on the second sample may be identical or different from that carried out on the first sample.

Role of rapid screening tests in HIV infection screening and laboratory diagnosis strategies in France

These conclusions relate to the role of RSTs in HIV infection screening and laboratory diagnosis strategies, excluding auto-tests (which the National Ethics Advisory Committee and the National AIDS Council published concurring opinions on in November and December 2004).
A distinction should be made within these conclusions between those which are guidelines and those provided for guidance in anticipation of the results from the experiments planned to be carried out in France.

As part of these conclusions, a rapid screening test (RST) is defined as a single test, interpreted subjectively, easy to perform and designed to give a result within a short period of time (usually less than 30 minutes) when it is performed on the patient. It can be carried out using whole blood, saliva, serum and plasma, depending on the matrix/matrices required by the manufacturer for its product. It is used to detect anti-HIV-1 and anti-HIV-2 antibodies.

Initial considerations and general principles

Based on their current performance, acceptability and potential benefits, the RSTs available on the French market in 2008 and with CE marking offer a valuable tool to supplement the traditional screening model based on the use of ELISA tests, thereby helping achieve two main objectives:

- obtaining a rapid diagnosis in certain emergency situations so that appropriate management can be initiated;
- facilitating access to knowledge about the serological status and to the options for preventive and therapeutic management of the HIV infection for certain groups of the population who have inadequate or even no access to the traditional screening system.

Following an analysis of the literature available and in agreement with the working group, guidelines have been drawn up on the use of RSTs in certain medical emergency situations.
However, difficulties with the transposition of the results from the studies that have primarily been carried out in the US, the limitations of these studies and the lack of epidemiological data in France making it possible to characterise the target populations have meant that guidelines could not be drawn up straightaway on the use of RSTs with a view to reducing the obstacles to screening. In view of the RSTs' potential valuable role in facilitating access to screening in both a medical and non-medical context, guidance is offered, calling for projects to be implemented involving a structured evaluation in order to confirm the expected benefits in France.

No matter the circumstances in which RSTs are used, two general principles stipulated as part of conventional HIV infection screening are applied in the same way to RSTs :

1) an RST can only be carried out with the informed consent of the person being offered the screening[3]

[4] Except in life-threatening emergencies where the person is unable to give their consent.

2) an RST can only be carried out in accordance with the general conditions of use which are subject to the specific guidelines indicated below, especially after a quality assurance system has been introduced.

Guidelines on the use of RSTs in medical emergency situations

It may be useful for an RST to be carried out on whole blood or serum/plasma (according to local conditions) by a healthcare professional working in a healthcare provision centre (emergency department, hospital unit, maternity ward etc.) in the following emergency situations, after obtaining the informed consent of the person affected:

- *Accident involving occupational exposure to blood*: an RST may be offered to the source patient.
- *Accident involving sexual exposure*: an RST may be offered to both partners in the emergency department or as part of the systems for managing accidents involving exposure to biological fluids.
- *Childbirth involving pregnant women whose HIV serological status is unknown or pregnant women who have had suspected HIV exposure since the last screening test was carried out during their pregnancy*: an RST may be offered to the pregnant woman.
- *Diagnostic emergency due to the occurrence of an acute pathology suggesting the AIDS stage*: an RST may be offered to the patient.

In all these cases, a combined ELISA test will have to be carried out as quickly as possible, whatever the results of the RST.

Guidance on the use of RSTs in populations inadequately covered by the traditional screening model

The use of RSTs may be suggested in order to:

- facilitate access to screening for populations which have inadequate access to the current system in relation to their risk exposure for a variety of reasons (in particular, populations which avoid institutions, are marginalised, are outside the healthcare system, have no entitlement to social security etc.) ;
- improve access to screening results.

This use can be provided for within traditional screening provision structures (free, anonymous screening centres (CDAG), centres for information, screening and diagnosis of STDs (CIDDIST) etc.) or within alternative structures. The RST can be offered using whole blood or saliva by healthcare professionals and other qualified persons. In every case, the use of RSTs must be included as part of a structured evaluation approach.
The use of RSTs should therefore be adopted as part of implementing projects. These projects will have to be based on hypotheses documented by their promoters and envisage a systematic evaluation approach. This evaluation will have to help confirm the expected benefits of using RSTs in the exact circumstances relating to each type of project and for the defined target populations, based on criteria adapted to the objectives being pursued.
The results of these evaluations will be instrumental in drawing up guidelines on those circumstances where RSTs are currently used in practice in France.

Guidelines on the general conditions for using RSTs

Implementing a quality assurance system.

In every case, the use of RSTs must be supported by the implementation of a quality assurance system in order to limit any risk of error when handling and interpreting these tests and to guarantee the quality of the results obtained.
This system must systematically ensure:

- the initial verification of the qualifications of the staff entrusted with carrying out the RSTs and regular assessment of their skills;
- the implementation of a training programme for staff carrying out RSTs;
- guaranteed traceability of the RSTs used and their results;
- access to a support network and medical care for any person who might receive a positive screening result.

It will be possible to adapt each of these elements according to the actual features of the relevant screening institutions.
The precise definition of a technical specification for implementing a quality assurance system in conjunction with the use of RSTs must be examined within a specific working group.

The current legal framework only permits blood or saliva samples to be taken by doctors and midwifes or, when prescribed and using certain methods, by nurses and staff in medical analysis laboratories. The use of RSTs in institutions closest to the populations targeted by authorised non-healthcare professionals (association volunteers, social workers etc.) can only be envisaged within the projects described above.

Rapid screening algorithm

RST results should be interpreted taking into account the clinical and epidemiological context. A negative RST result can be considered as excluding any HIV infection, except if the patient has been recently exposed within less than three months. In this situation a new HIV serological test will have to be carried out using a combined ELISA test according to the general scheme defined in the previous guidelines.
Any positive RST result must be confirmed by a WB or IB, based on the scheme defined in these guidelines, in order to eliminate a false positive result.
In the case of an invalid result (uninterpretable RST), a combined ELISA test will need to be carried out according to the general algorithm defined in the previous guidelines.

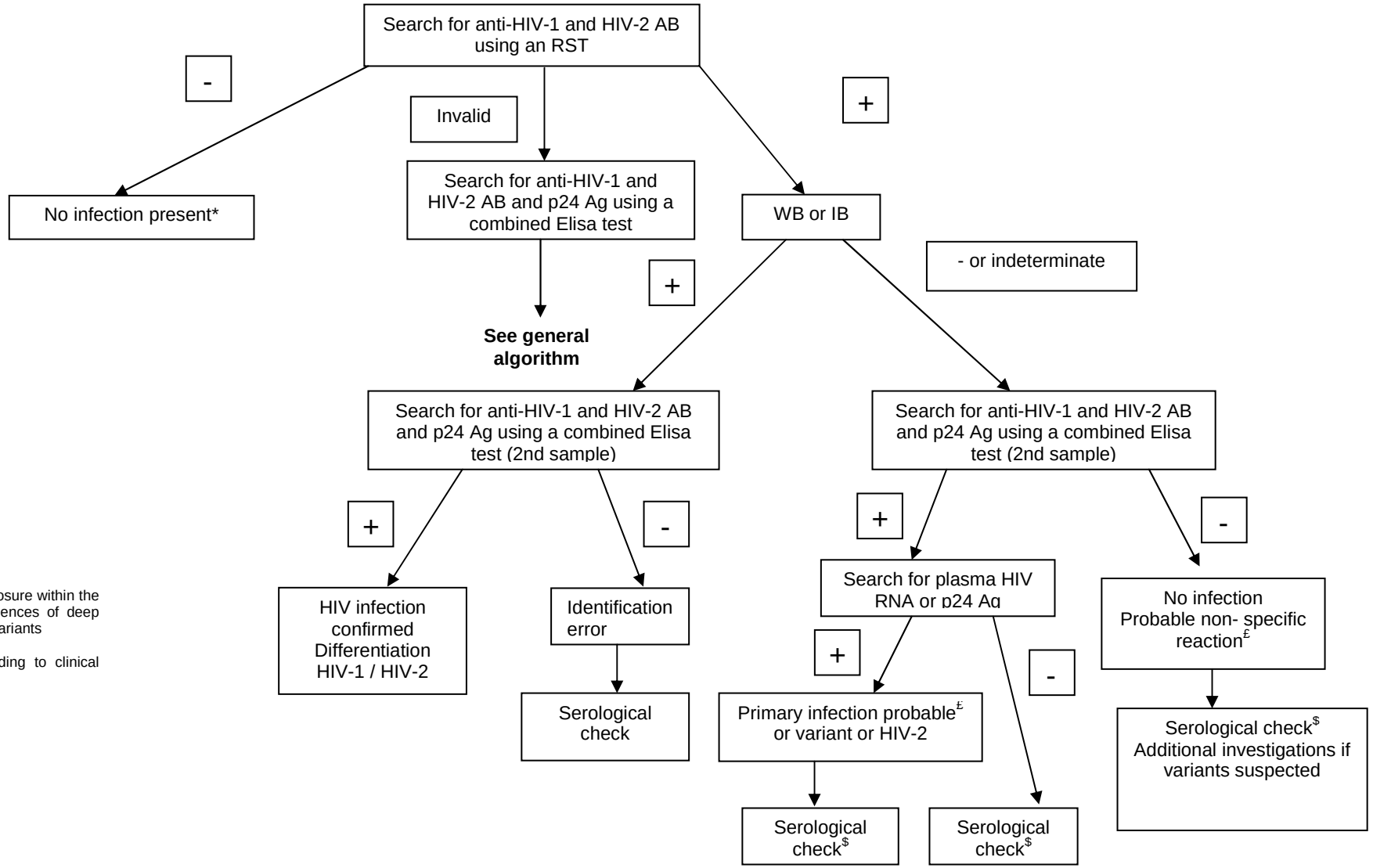
Issuing the results of an RST

The results must be issued in the form of a “positive/negative search”. A standardised procedure must be provided for giving the results to the patient in the form of a signed written document (specifying the type of sample taken, the nature of the test and its name, the result and the limits of this result). The result of the screening test and its interpretation must be mentioned.

Information

The provision of suitable information must allow, in every case, at least to guarantee informed consent to the rapid screening test and the patient's understanding of the rapid screening process. Anyone taking an RST must be informed in particular that the results of the test may be given to them during the same visit. Above all, an explanation must be given about the meaning of a negative result, invalid result and positive result, and about the need, in the case of the latter result, to carry out a confirmation test involving a blood sample being taken at a medical institution.

SCREENING ALGORITHM
FOR RST
ADULTS AND CHILDREN AGED OVER 18 MONTHS



* unless suspected HIV exposure within the previous 3 months or incidences of deep immunodepression or rare variants
$ 1 to 2 weeks later
£ To be interpreted according to clinical context
+ : positive result
- : negative result
AB : antibody

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Scientific societies, professional associations and institutions

The following scientific societies, professional associations and institutions were asked to participate in drafting these guidelines

- ACT UP-PARIS
- Agence française de sécurité sanitaire des produits de santé (AFSSAPS)
- AIDES
- Association Des Epidémiologistes de Langue Française (ADELF)
- Collège des économistes de la santé (CES)
- Collège des Universitaires de Maladies Infectieuses et Tropicales (CMIT)
- Collège Français de Médecine Générale (CFMG)
- Collège National des Généralistes Enseignants (CNGE)
- Collège National des Gynécologues Obstétriciens Français (CNGOF)
- Collège National des Sages-Femmes (CNSF)
- Comité Consultatif National d'Éthique des sciences de la vie et de la santé (CCNE)
- Conseil National du Sida (CNS)
- Fédération nationale des associations de sages-femmes (FNASF)
- Fédération Nationale des Collèges de Gynécologie Médicale (FNCGM)
- Institut National de Prévention et d'Education pour la santé (inpes)
- Institut National de la Transfusion Sanguine (INTS)
- Institut de Veille Sanitaire (InVS)
- Sida Info Service (SIS)
- Société de Formation Thérapeutique du Généraliste (SFTG)
- Société de Pathologies Infectieuses de Langue Française (SPILF)
- Société Française d'Immunologie (SFI)
- Société Française de Biologie Clinique (SFBC)
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