Superior Health Council

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Decentralised and demedicalised screening for HIV in Belgium: response to a request for advice from the public health authorities.

This advisory report aims at providing the Belgian public health authorities, medical and non-medical professionals, not-for-profit organisations or associative structures involved in the prevention of STIs/AIDS with specific recommendations regarding the precise circumstances under which decentralised and demedicalised screening for HIV should be performed in Belgium.

July 2015

1. INTRODUCTION AND ISSUES

On 25 June 2014, the Superior Health Council (SHC) received a new request for advice from the former Federal Minister of Public Health regarding the setting in which decentralised and demedicalised screening for human immunodeficiency virus (HIV) should be performed in Belgium ("*Mag ik u vragen een richtlijn uit te werken betreffende de context waarbinnen die gedecentraliseerde en gedemedicaliseerde screening dient te gebeuren* ?" (*sic*)).

The background and framework of this advisory report are based on the most recent WHO[1] and ECDC[2] recommendations and guidelines concerning HIV-testing strategies (see section 4. References) as well as on the Belgian "National HIV-plan", which was presented in October 2013 and spans from 2014 to 2019. This plan sets out a series of prerequisites for decentralised and demedicalised testing strategies. Definitions for the decentralised and demedicalised HIV-testing strategies referred to in this advisory report are provided in section 3.2.

The information that should be provided within the framework of an HIV-testing strategy includes the following: how to counsel participants, where to find entry points (places where samples are collected), what type of test is used, and how to communicate the test results. Under its "strategy principles", the National HIV-plan mentions that HIV-testing is a transversal issue (p. 21, English version). Still, the SHC wishes to put particular emphasis on the importance of linkage to care, which needs to be an integral part of the testing procedure.
The HIV-plan addresses three specific action points that concern decentralised and demedicalised testing:

- "Support decentralised and demedicalised screening" (Screening and access to care, point 9; p.23, English version)
- "Establish a legal framework for decentralised and demedicalised screening" (Screening and access to care, point 10; p.23, English version)

[1] World Health Organisation
[2] European Centre for Disease Control and Prevention

- "Develop community-based screening services with the local ARL[3]/ARC[4] and guarantee fast and appropriate access to care, treatment and support services" (Screening and access to care, point 15; p.24, English version)

The current state-of-the-art HIV-testing strategy is a medicalised and centralised strategy, i.e. one that is conducted by a healthcare professional in a clinical setting. This state-of-the-art strategy uses laboratory tests (enzyme immunoassays, immunoblot) on blood samples, and the final test results are communicated during a face-to-face consultation with a physician/healthcare professional.

It is important to emphasize that for most people (including minors), this strategy remains the preferred option for undergoing HIV-testing. Decentralised and demedicalised strategies should only be used for people who would otherwise fall through the cracks of the current strategy, such as described in the Belgian National HIV-Plan of 2013[5] and the ECDC guidance on HIV-testing of 2010 (see Section 4. References). In the ECDC report, the authors look at different ways to overcome barriers to HIV-testing (at the level of the individual, that of the healthcare provider, and at the institutional level), as well as at strategies to increase the uptake of HIV-testing, such as simplifying the consent procedure, describing alternatives for (pre- and post-test) counselling, using alternative HIV-testing technologies, and ensuring access to care.

In recent years, a series of programmes that offer alternatives to several aspects of the existing state-of-the-art strategy have been developed and pilot-tested. These alternatives include the following: collecting samples during outreach activities, using HIV rapid tests, using oral fluid samples (instead of blood samples), communicating the results of the orientation tests by telephone/text messaging/the internet, and involving non-healthcare professionals, who could facilitate, and even participate in the process of HIV-testing. Each of these elements will be discussed in detail in this document.

[3] AIDS Reference Laboratory

[4] AIDS Reference Centre

[5] MSM (Men who have sex with men), migrants, injecting drugs users, young people, sex workers, prisoners, etc.

2. ADVICE

Foreword

The Minister's request is inconsistent with the provisions of Royal Decree no. 78 of 10 November 1967, which prohibits "decentralised and demedicalised screening". The SHC therefore advises the competent authorities to amend the relevant legislation regarding the practice of health professions, including this Royal Decree.

Definitions

The first step in describing the conditions under which "decentralised and demedicalised screening" should be carried out is to provide a clear definition of what is meant by the terms used. Indeed, their significance varies depending on the setting considered as well as the intended goals (laboratory, medical setting (doctor's surgery), external environment, etc.). To avoid any misunderstanding, section 3.2 of this advisory report provides an account of the meanings in which the SHC uses these and other directly related terms.

The SHC takes the view that the population should be given full information on this issue. Yet there is a great deal of confusion regarding the use of these terms by service providers, on the internet, by the industry, etc. Thus, the Belgian public health authorities should to be aware of the need to provide a clear and official (legal) definition of the different test strategies available as well as of all the terms used in connection with them.

Orientation test

The SHC suggests that the newly-coined term "orientation test" should be used in HIV-testing programmes to reflect the indicative nature of results obtained with tests that are conducted in a manner that is not in keeping with state-of-the-art strategies, as described in the definitions (section 3.2).
It should be pointed out that the negative predictive values for rapid tests (on blood) in most of the studies available range from 99,7% to 100% and that the positive predictive values (also on blood) range from 67% to 99,5% (data available for high-seroprevalence populations in Africa). Only the rapid tests on blood have been validated.

Implementation and evaluation

As a preliminary requirement, the pre-test stage of such screening projects should be standardised. Given the fact that this is a process that concerns both the medical dimension as well as the aspects pertaining to laboratory work and the at-risk communities, the SHC recommends that a "steering committee" (with experts and representatives of the ARL, ARC, NGOs[6], etc.) be set up. This committee should be tasked with assessing the appropriateness of a programme in which decentralised and demedicalised screening is to be offered by one of the structures authorised to do so.

Next, the data should be collected and processed (linkage to care, monitoring ...) within a single, broadly active structure. The current programme need to be harmonised (integrated care). In fact, this overarching approach will make it possible to assess the quality of what has been implemented. At the moment, the Belgian Scientific Institute of Public Health (IPH) is the only scientific institution that is in a position to centralise these epidemiological data and to ensure the exchange of information with the relevant European structures. The SHC therefore also advises the federal competent authorities for health to act accordingly, by taking into account the information and proposals it has issued.

[6] Non-governmental organisation

Training

Given the context in which decentralised and demedicalised screening is carried out, it is necessary to gain insight into the level of quality thus achieved. This requires the setting up of a quality assurance system for decentralised and demedicalised screening.
Therefore, the SHC advises the Belgian public health authorities to launch a specific continued training programme for those concerned. More specifically, such training should be aimed at healthcare professionals as defined in the legislation as well as volunteers/employees who do not pursue a healthcare profession in the legal sense, but who are active in a not-for-profit prevention or associative structure involved in providing psychosocial support to the affected key populations as well as in engaging in STI[7]/AIDS[8] prevention activities (as well as related medical issues) (cf. section 3.4). As regards orientation-test based HIV/AIDS screening, all those involved must have received specific training on HIV-testing from a medical structure specialised in HIV (in cooperation with - or even following the initiative of - other structures related to the key populations). Yet they must also complete continued training on HIV/AIDS infection provided by the same medical structures. The responsibility for issuing a certificate (with accreditation) upon completion of the training programme rests with the specialised medical structure. Appendix 2 of this document makes a first suggestion as regards the content of this training programme (theoretical and practical component), for general information.

Information

To the "healthcare contacts" (see section 3.4):

The SHC advises that prior to implementing a programme that uses alternative HIV-testing strategies, an information booklet should be made available that provides a detailed description of the project. At the very least, this booklet should contain a section on the methods used (setting, target population, procedures for taking the samples, carrying out the tests, communicating the results, counselling and ensuring linkage to care), as well as on ethical issues (and how they are dealt with) and on data management and confidentiality.

To the participant:

The SHC advises that prior to implementing a programme that uses alternative HIV-testing strategies, the participants should be provided with detailed, written information on the procedures, ethical issues, as well as on data management and confidentiality. They should also be given information on the limits inherent in such testing.

Keywords: HIV, AIDS, Mass screening/methods, key populations, HIV testing, HIV testing policy, linkage to counselling, linkage to care, post-test services, rapid HIV test, demedicalised HIV testing, decentralised HIV testing, HIV Self-sampling, HIV self-test.

[7] sexually transmitted infections
[8] acquired immune deficiency syndrome

3. FURTHER DETAILS AND ARGUMENTATION

List of abbreviations

Ag	Antigen
AIDS	Acquired immune deficiency syndrome
ARC	AIDS Reference Centre
ARL	AIDS Reference Laboratory
CBO	Community-based organisation
CD4	cluster of differentiation 4
CDC	Centers for Diseases Control and Prevention
CE	Conformity marking for certain products sold within the European Economic Area since 1985.
ECDC	European Centre for Disease Prevention and Control
GP	General practitioner
HCS	Healthcare system
HIV	Human immunodeficiency virus
IPH	Scientific Institute of Public Health (Belgium)
MSM	Men who have sex with men
NGO	Non-governmental organisation
PEP	Post-exposure prophylaxis
SHC	Superior Health Council (Belgium)
STI	Sexually transmitted infections
UK	United Kingdom
VL	Viral load

3.1. Methodology and procedure

After analysing the request, the Board and working group Chair identified the necessary areas of expertise. The working group experts provided a general and an *ad hoc* declaration of interests and the Committee on Professional Conduct assessed the potential risk of conflicts of interest.
After a plenary meeting, the working group divided the work over three subgroups ("Definitions", "Training" and "Pre/post-test information"). A specific chapter has been devoted to each of these issues, more details on which will be provided below.

This advisory report is based on scientific literature published in scientific journals and in reports from relevant national and international organisations, as well as on the consensus opinion of the experts. The background and framework of this advisory report are based on the most recent WHO and ECDC recommendations and guidelines concerning HIV-testing strategies (see section 4. References) as well as on the Belgian "National HIV-plan", which was presented in October 2013 and spans from 2014 to 2019.

Once the draft advisory report was approved by the working group, it was ultimately validated by the Board during a plenary meeting.

3.2. Definitions of the terms used in this specific context

The definitions provided below only apply to this advisory report. In another context, these terms may be used to refer to a somewhat different content.

Centralised HIV-testing
Centralised HIV-testing refers to any test **which is conducted** in a clinical setting.

Decentralised HIV-testing
Decentralised HIV-testing refers to any test **which is not conducted** in a clinical setting (e.g. community-based testing).

Medicalised HIV-testing
Medicalised HIV-testing refers to HIV-testing carried out by a physician as established by the Royal decree n°78 of 10 November 1967.

Demedicalised HIV- testing
Demedicalised HIV-testing refers to any test which is not carried out by or under supervision of a physician as established by the Royal decree n°78 of 10 November 1967.

Clinical setting
The term "clinical setting" refers to the location or setting generally used for healthcare purposes (including home visits by a general practitioner {GP}).

Standard of care for testing
"Standard of care for testing" for HIV are tests that meet the current scientific standards applied in Belgium.

Screening test
The term "screening test" is used to refer to any enzyme immunotest conducted inside a medical laboratory in accordance with the "Standard of care for testing".

Orientation test
The term "orientation test" refers to any immunotest that does not meet the Belgian "Standard of care for testing" and therefore requires a confirmation strategy in an AIDS Reference laboratory in accordance with the "Standard of care for testing".

Confirmation test
The term "confirmation test" refers to any test that is used to confirm a reactive screening test (Western Blot, line immunoassay, etc.). In accordance with the "Standard of care for testing", this confirmation test has to be carried out by an AIDS Reference laboratory on a blood sample.

HIV-testing
"HIV-testing" refers to the process during which (1) samples are taken among affected key populations or individuals who consider themselves at risk (2) the screening test is performed on these samples, and (3) the confirmation procedure is carried out in the event of these results being reactive.

Self-test
The term "self-test" (also called "home test") is used to refer to any orientation test that is requested, performed and interpreted by the consumers/patients themselves, usually without medical assistance. A reactive test result from a self-test should always be confirmed on a blood sample. These tests should be CE[9]-marked for self-testing.

Self-sampling
The term "self-sampling" (also called "home-sampling") is used to denote the sampling procedure performed as part of the HIV-test strategy. It indicates that the consumers/patients take these samples on their own. Samples collected in this manner should be sent to the laboratory for testing. In the event of the test result being reactive, the latter should always be confirmed, which is why these tests are to be looked upon as orientation tests.

[9] Conformity marking for certain products sold within the European Economic Area since 1985

Information booklet
The SHC advises that prior to implementing a programme that uses alternative HIV-testing strategies, an information booklet should be made available that provides a detailed description of the project to the "healthcare contacts" (see section 3.4). At the very least, this booklet should contain a section on the methods used (setting, target population, procedures for taking the samples, carrying out the tests, communicating the results, counselling and ensuring linkage to care), as well as on ethical issues (and how they are dealt with) and on data management and confidentiality.

Patient information sheet
The SHC advises that prior to implementing a programme that uses alternative HIV-testing strategies, the participants should be provided with detailed, written information on the procedures, ethical issues, as well as on data management and confidentiality. They should also be given information on the limits inherent in such testing.

Linkage to care
Optimal or good linkage to care is defined as the patient attending a medical consultation for specialized HIV-care within 3 months after HIV-diagnosis (CD4[10] and VL[11] records can be used as measuring tools).

References :
Delaugerre C. & Simon F., 2012 ; HAS, 2008 ; *Journal Officiel de la République Française*, arrêté du 9 novembre 2010 ; CNS, 2012 ; CNE, 2013 ; Public Health England, 2014.

Translation board

In order to avoid any misunderstanding or possible misconception, the following table clarifies the meaning (in French and in Dutch) of the specific terms that are used in this document and have been validated by the experts.

Source	Meaning in French	Meaning in Dutch
Confirmation test	Test de confirmation	Confirmatietest
HIV-testing	Test VIH	hiv-test
Orientation test	Test d'orientation	Oriëntatietest
Screening test	Test de dépistage	Screeningstest
Self-test	Auto-test	Zelftest
Self-sampling	Auto-prélèvement	Self-sampling

[10] cluster of differentiation 4 (cell surface molecules present on leukocytes)
[11] viral load

3.3. Pre-test and post-test information

It should be noted that the Minister's request is inconsistent with Royal Decree no. 78 of 10 November 1967, which does not provide for "decentralised and demedicalised screening". The SHC therefore advises the competent authorities to amend the relevant legislation regarding the practice of health professions, including the Royal Decree in question.

Demedicalised and decentralised HIV-screening strategies cause a paradigm shift: indeed, since HIV-tests were first introduced, those taking them have only received their final test results once the first screening test, if reactive, has been confirmed.

When using an orientation-testing strategy:

- If the test result is reactive: it is important that the patient information sheet should state explicitly that the result communicated needs to be confirmed on a blood sample. The SHC therefore suggests using the term "reactive" rather than "positive" test results to avoid any confusion.
- If the test result is non-reactive: clear information needs to be provided on the window period, which differs depending in the test and specimens used.

Pre-test information

Pre-test information can be provided in several ways, depending on the needs of the affected key population or specific target group. It can be provided individually or to groups by a healthcare professional, a trained volunteer or peer, or using validated media materials (video) for specific target groups, and should include information on the window periods and the symptoms of primary infection.

This pre-test information should provide clear explanations on the procedures, on how to access the results, and on the fact that the decision to undergo testing is a voluntary one.

When implementing a demedicalised and/or decentralised programme for HIV-testing, the participants should be given clear and understandable information that is tailored to their needs and also takes into account the following:

- The settings where samples are collected (non-exhaustive list):
    - GP's surgery (family doctor);
    - Other medical facilities (emergency departments, gynaecological consultations, private laboratories, etc.);
    - Outreach activities;
    - Civil society organisations (NGOs or CBOs[12]);
    - On-line tests;
    - At home (self-tests).
- The sample that is collected (non-exhaustive list):
    - Blood sample: whole blood, serum, plasma, dried blood spot, dried plasma spot, collected through venous puncture or finger prick;
    - Oral fluid (saliva) sample.

[12] Community-based organisation

- The location at which the test is conducted:
    - Clinical setting (see section 3.2 for definition);
    - Civil society organisations;
    - Laboratory;
    - At home;
    - During outreach activities.
- The timing and manner in which the test results are communicated (non-exhaustive list):
    - On site (when using rapid tests);
    - During a face-to-face consultation (with physician, trained counsellor, or peer);
    - On-line communication: only by using state-of-the-art protection measures to secure the data (e.g. with a personal password);
    - Communication over the telephone: only by using state-of-the-art protection measures to secure the data (e.g. with a personal password);
    - Text-messaging: only by using state-of-the-art protection measures to secure the data (e.g. with a personal password).
- What to do in case of a reactive/non-reactive result:
    - Refer to medicalised testing and provide information on financial implications;
    - Ensure access to counselling services;
    - Provide information on the window periods;
    - Provide information on the orientation tests and on the predictive value of testing.
- Referral to a facility that offers post-exposure prophylaxis in case of exposure < 48-72 hours.
- Referral to a facility that offers the most up-to-date HIV-test (currently the 4th generation HIV-test), a single HIV antigen test and or an HIV VL on blood in case of symptoms suggesting a primary infection.
- How to reassure participants as regards the confidentiality of their information.

Post-test information

The test result should be communicated to the participant as agreed and delivered with empathy. The information provided should be clear and understandable to non-medical professionals.

All necessary precautions need to be taken to ensure the results are disclosed to the right person. If the channel chosen for delivering these results is the internet, a personal password and/or specific sample code should protect the test results from being accessed by anyone other than the participant in question.

Considerable emphasis should be placed on the fact that reactive test results need to be confirmed for the diagnosis to be reliable. Yet, though a reactive orientation test has no final diagnostic value, the SHC is aware that such results are likely to have a considerable emotional impact on those concerned. Therefore, great attention should be paid to the appropriate timing

chosen for disclosing the tests results, especially when this is not done face-to-face. Indeed, it is crucial that individually tailored support be available to those who receive a reactive result. It will need to be of two kinds, viz. counselling and linkage to care. Counselling may be provided by healthcare professionals, trained non-healthcare professionals or trained peers or volunteers. Linkage to care and access to treatment "*must be guaranteed regardless of patient's legal or administrative status*" (Belgian National HIV-Plan, English version, p21). The support provided will also be used as a tool on the basis of which each programme that implements a decentralised and demedicalised strategy (as described in section 3.2) will be assessed.

Initial counselling may be offered during a face-to-face encounter, over the telephone or on line (by a trained non-healthcare professional, peer, trained volunteer or healthcare professional). Subsequently, the participants should always have the possibility of receiving personal (face-to-face) counselling. Counselling should be easily accessible and free of charge. Facilitating linkage to care is the second pillar in the support provided to the participants of demedicalised and decentralised HIV-testing strategy programmes.

To this end, the project contact person, who communicates the result, will do either of the following:

- provide a document describing the process followed so far as well as the future course of action, or
- contact the medical facility at which the participant will collect the confirmatory test results.

Within such a programme, care should be taken that it is easy to reach a contact person, that the test results are properly communicated and that linkage to care is highly accessible.

As regards participants with non-reactive tests, they should be provided with information on the following issues:

- prevention (also as regards oral sex);
- window periods (considering the fact that the sensitivity of the rapid tests may be very low);
- the symptoms of a primary HIV-infection;
- facilities that offer post-exposure prophylaxis treatment and the most up-to-date HIV-test (currently the 4th generation HIV-test), an HIV antigen test and/or an HIV VL test on a blood sample;
- the importance of testing for other STIs.

Summary

Pre-test information (patient information sheet): This information sheet should:

- clearly explain the programme procedures, including its decentralised and/or demedicalised components;
- mention explicitly how the samples are collected, which test is used, its limitations and how the results will be communicated;
- point out that participation is voluntary and that participants have the right to withdraw at any stage of the programme;
- provide information on the window period for each test;
- provide clear information on the fact that a reactive test result has no diagnostic value, and should therefore be confirmed.

Post-test information:

- Apart from ensuring that the test results are communicated to the programme participants in a manner that is both understandable to them and tailored to their needs, a decentralised and/or demedicalised screening strategy should pay close heed to implementing the following components:
  - a highly accessible counselling strategy, where the programme participants can receive proper, individually tailored counselling from a trained volunteer, peer or healthcare professional;
  - a strategy aimed at facilitating linkage to care for participants with a reactive result. Since confirmation is necessary to obtain a diagnostic result, it is crucial that participants are guided towards a healthcare facility that can provide such confirmation.

3.4 Education and practical training of non-healthcare professionals conducting HIV-testing (also called *healthcare contacts*)

Any (non-)healthcare professional offering orientation-strategy based HIV-testing should receive training to develop a range of competencies in relation to the HIV-test. Such training should guarantee that the "quality of care" provided by the trained volunteer/peer equals that of the care delivered by a healthcare professional. The training should also prepare the volunteer/peer to deal with the participants' fears during the testing process. Therefore, the training programme should cover the following topics as well as the technicalities of the project he/she will be involved in:

- Pre- and post-test counselling;
- Psychological means to mitigate the impact of a positive HIV-orientation-test result;
- Ethics and confidentiality;
- Information on the national health system, including organisations active in the field of HIV;
- Linkage to care;
- Raising awareness and providing information on facilities that offer post-exposure prophylaxis in case of exposure < 48-72 hours;
- Raising awareness and providing information on facilities that offer the most up-to-date HIV-test (currently the 4th generation HIV-test), an HIV antigen test or an HIV VL test on blood in case of symptoms suggesting a primary infection.

As pointed out in the general introduction to this document, the "National HIV-Plan 2014-2019" aims - through its actions no. 37 and 38 - to "develop a national screening strategy for HIV and STIs in accordance with existing regulations" and to "improve screening by general practitioners and specialists", respectively.

In order to provide proper "support [to such] decentralised and demedicalised screening", it is advisable that the latter be carried out "with properly trained (non-medical) personnel". These members of staff will be required to conduct one of several existing orientation tests.

Who can carry out an orientation test and therefore undergo training on this subject:

- The following healthcare providers, listed in Royal Decree No 78 of 10 November 1967 pertaining to the healthcare professions, mainly ($^{(*)}$: appointed personnel providing medical services {*acte délégué - gedelegeerde handeling*}):
  - Physicians
  - Pharmacists
  - Specialists in medical biology (physicians or pharmacists, in Belgium)
  - Midwives$^{(*)}$
  - Nurses$^{(*)}$
  - Clinical-biology laboratory technologists$^{(*)}$
- As well as: volunteers/employees who do not pursue a healthcare profession in the legal sense above, but who are active in a not-for-profit prevention or associative structure involved in providing psychosocial support to key populations as well as in engaging in STI/AIDS prevention activities (of related medical issues).

All the individuals mentioned above must have received specific preliminary training on orientation-test based HIV/AIDS-screening. This training should be organised by a medical structure specialised in HIV (in cooperation with - or even following the initiative of - other structures related to the affected key populations). Yet they must also complete continued training on HIV/AIDS-infection provided by the same structures. The responsibility for issuing a certificate (with accreditation) rests with the specialised medical structure.

Training goal:

The specific training programme on orientation-test based HIV-screening aims to:

- Fill the knowledge gap regarding the risks and modes of transmission of STIs/HIV (medical problems in the broad sense) in the key populations.
- Enhance the ability to conduct prevention interviews tailored to the needs of the key populations and to carry out pre- and post-test interviews.
- Acquire the necessary knowledge and skills for the use of orientation tests.

Training: This training programme has two components, viz. a theoretical and a practical component.

1° ***Theoretical component***

Offering this part of the training programme (theoretical component) on line may be taken into consideration.

As a minimum requirement, this theoretical component should cover the following issues (cf. also appendix 2 for more detailed information on each of the topics described):

1) Legal and ethical issues related to such screening;
2) HIV-infection;
3) Orientation tests for HIV;
4) Data recording;
5) Hygiene and safety requirements when conducting orientation tests;
6) The safety and management of medical waste;
7) Pre- and post-counselling training (including linkage to care);
8) Quality assurance;
9) The Belgian healthcare systems, more specifically the aspects that pertain to the care and treatment provided for HIV, including the referral system for specialist care and aid organisations;
10) Basic information on communication with and socio-psychological aspects of the affected key populations (including intercultural aspects).

2° ***Practical component***

This part of the training programme cannot be offered on line.

- At least five orientation tests for HIV must be carried out within an official reference centre (sampling, including the management of the equipment used, waste management,

reading and interpretation of the test results) under the supervision of an experienced healthcare professional.

- Attend several practical screening sessions (person-to-person contact, outreach situations) or simulated situations at the official reference centre: pre- and post-test information settings (including receiving people from key populations, conducting interviews, sampling, reading the test results, accidental exposure,...) . These sessions should also make it possible to gain a first-hand insight into the appropriate manner in which the test results should be delivered (pre- and post-counselling).

Upon completion of the training, the accredited training centre issues a training certificate (with accreditation).

4. REFERENCES

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  http://apps.who.int/iris/bitstream/10665/75206/1/9789241593877_eng.pdf

  In vitro diagnostics and laboratory technology. Simple / Rapid tests.
  http://www.who.int/diagnostics_laboratory/faq/simple_rapid_tests/en/

5. COMPOSITION OF THE WORKING GROUP

The composition of the Committee and that of the Board as well as the list of experts appointed by Royal Decree are available on the following website: composition and mode of operation.

All experts joined the working group ***in a private capacity***. Their general declarations of interests as well as those of the members of the Committee and the Board can be viewed on the SHC website (site: conflicts of interest).

The following experts were involved in drawing up and endorsing this advisory report. The working group was chaired by **Yves VAN LAETHEM**; the scientific secretary was Jean-Jacques DUBOIS.

BOTBOL-BAUM Mylène	Biomedical ethics	UCL, HELESI & IRSS
DEBLONDE Jessika	Infectious diseases	WIV-ISP
DELFORGE Marie-Luce	Medical microbiology	ULB-Erasme, Laboratoire de Référence SIDA.
DEMOL Jacques	Psychology	ULB, CHU Brugmann
DE MOL Patrick	Medical microbiology, infection control during care	ULg, CHU Sart-Tilman
DERDELINCKX Inge	Internal medicine, infectious diseases, HIV/AIDS.	UZ Leuven, ARC Leuven
FRANSEN Katrien	Clinical sciences	ITG, Aids Referentielaboratorium
GENNOTTE Anne-Françoise	Infectious diseases	CHU, Saint-Pierre, Cetim
GOFFARD Jean-Christophe	infectious diseases, HIV.	CHU Erasme, Centre de référence SIDA.
LEONARD Philippe	Internal medicine, infectious diseases, HIV.	ULG, CHU. Centre de référence Sida
LEQUARRE Françoise	Infectious diseases, HIV.	CHU-ULg, Centre de Référence Sida
MANIRANKUNDA Lazare	Public health, HIV-SAM Project	ITG, HIV-SAM Project
PLATTEAU Tom	Clinical sciences, sexology	ITG, HIV-STD Clinic
VAN LAETHEM Yves	Infectiology, vaccinology, HIV.	Hôpital St-Pierre, Bruxelles
VANDEKERCHOVE Linos	Internal medicine, infectious diseases, Clinical HIV.	UZ Gent, HIV-referentiecentrum
VAN GYSEGHEM Jean-Marc	Information, Law & society	UNamur, CRIDS
YOMBI Jean-Cyr	Internal medicine, infectious diseases, HIV.	UCL, Centre de Référence Sida

The following administrations and/or ministerial cabinets were heard :

CEUTERINCK Griet	Legal management, FOD Volksgezondheid
WILMOTTE Régine	Legal department, SPF Santé Publique

The following firms/associations/etc. were heard:

MARTIN Thierry	« *Plateforme Prévention Sida* » asbl [13]
ROMBOUTS Jean-Jacques	Vice-Chairman of « *Conseil National de l'Ordre des Médecins* ».
STURBOIS Anne-Sophie	Legal counsel at « *Conseil National de l'Ordre des Médecins* ».
VAN DEN EYNDE Sandra	" *Sensoa* " vzw [4].

[13] French-speaking non-profit organisation [4] Dutch-speaking non-profit organisation

Appendix 1: A few scientific facts on rapid tests (based on the recommendations of the WHO and of the NAM, for further details, see section "4. References").

RAPID TEST

- The term "rapid test" is used to refer to any screening/orientation test which provides a result in less than an hour. A reactive test result from a rapid test should always be confirmed by means of a blood sample. Rapid tests are less sensitive than the standard of care for testing, hence the reason why these are *orientation* tests.

- Rapid tests are designed for use in situations that require a preliminary screening test result. They are high-quality, easy-to-use tests, based on immuno-chromatographic and/or immuno-filtration techniques, quick (results obtained within 1 to 30 min max), easy to perform and require little or no additional equipment. They are designed to be used on a single or a limited number of samples and most of them can be stored at room temperature for extended periods of time.

- A reactive (positive) result is only preliminary and must be followed-up by a confirmatory strategy on blood.

- Substantial differences have been reported in the performance of different test kits. Most rapid tests detect antibodies only, but a test that also detects p24 antigen was introduced in 2009. However, its sensitivity is limited compared to that of standard screening tests.

- Rapid tests were first developed in the early 1990s for use in developing countries (where specialised laboratory facilities may not be available), and their uptake has varied significantly from one country to another. In the United States, the CDC has recommended their use with key populations since 1998, and they have been an integral part of the testing strategy since 2003. The UK testing guidelines are considerably more cautious: their use should be limited to clinical settings where a rapid turnaround of testing results is desirable, community testing sites, circumstances when venepuncture is refused, and for urgent source testing in cases of exposure incidents (e.g. before PEP {Post-exposure prophylaxis}).

What is the difference between an enzyme immunoassay and a rapid test?

Enzyme immunoassays are highly sensitive and specific and are able to detect HIV-1/ HIV-2 and variants. They require sophisticated equipment that must be regularly maintained, a constant electricity supply and skilled technicians. They are more suitable for testing large numbers of samples per day, as well as in blood banks or for surveillance studies. The rapid tests may be more suitable for emergency testing, and in smaller laboratories with low numbers of tests per day, or for outreach testing.

Important

- If there is a significant risk of recent infection, rapid tests should not be used exclusively, but should be used in addition to a more sensitive test.

- A reactive result, as with a reactive result to any other test, requires further testing to confirm the diagnosis. Before testing, patients will need to be informed of this. Staff using rapid tests will need training on how to explain reactive results, and how to support patients who receive them.

- A negative result is usually considered conclusive and does not require follow-up testing. However, because of the window period, it is advisable for someone with possible recent exposure to HIV to be sent to a facility that offers the most up-to-date HIV-test (currently the 4th generation HIV-test), an HIV Ag test and/or an HIV VL test on a blood sample.

Appendix 2: Suggestions for a formal certifying training programme.

Training programme: This training programme has two components viz. a theoretical and a practical component.

1° ***Theoretical component***

Offering this part of the training programme (theoretical component) on line may be taken into consideration.

This appendix specifies the minimum requirements for the training offered to future healthcare providers, viz. the 10 key issues that will need to be covered. In addition, it offers a non-exhaustive list of possible topics that could be addressed in the context of each of these issues. The latter are intended for illustrative and informational purposes only, and must be made to fit the situations encountered.

1) Legal and ethical issues related to such screening

- Providing information to those concerned;
- Informed consent;
- Doctor-patient confidentiality and secrecy, privacy principles for personal information (Protection of Privacy Act);
- Patient Rights Act.

2) HIV-infection

- Epidemiology;
- Specific issues related to the key populations;
- Modes of transmission, risk taking, key populations, prevention;
- Definition and symptoms of HIV-infection (recognising the symptoms of primary infection), AIDS (warning signs during the anamnesis and physical appearance);
- Definition antigen/antibody, natural history of the infection, window period;
- Screening algorithms;
- Other STIs and "associated" infections: symptoms, prevention, treatment principle;
- Pre- and post-test information (see section 3.3).

3) Orientation tests for HIV

- Different types of tests, their characteristics, sensitivity, specificity, positive and negative predictive value;
- Storage conditions;
- How to use and carry out the tests;
- Interpreting the results.

4) Data recording

5) Hygiene and safety requirements when conducting orientation tests

- Asepsis and hygiene requirements during sampling;
- Safety rules to avoid all blood-borne contamination when performing the test;
- Guidance in case of exposure to blood during sampling.

6) The safety and management of medical waste

- Safety principle: waste storage and disposal;
- Recommendations of the SHC on medical waste (SHC nr. 5109 of March 2005);
- Regional legislation on medical waste disposal.

7) Pre- and post-counselling training (including linkage to care).

- General information: definition of the notion "counselling", international recommendations, interview structure, attitude of the healthcare provider, ...
- Pre-counselling: knowledge on STIs/AIDS, sexual behaviour in key populations, risk reduction, risk scales, medical care, promoting safer sex, ...
- How to deliver the test results and ensure the link with care (linkage to care) and prevention;
- Post-*counselling*: information on delivering the test results, in the event of the latter being: reactive, non-reactive, indeterminate; condoms and lubricants, distribution of information booklets, how to offer and organise care, referral to a reference centre.

8) Quality assurance

- Initial and continued training;
- Standardised procedures;
- Process monitoring and traceability from patient registration to result delivery and post-test counselling;
- Internal and external quality control programs.

9) The **Belgian healthcare system**, more specifically the aspects that pertain to the care and treatment provided for HIV, including the referral system for specialist care and aid organisations.

10) **Basic information** on communication with and socio-psychological aspects of the affected key populations (including intercultural aspects).

2° ***Practical component***

This part of the training programme cannot be offered on line.

- At least five orientation tests for HIV must be carried out within an official reference centre (sampling, including the management of the equipment used, waste management, reading and interpretation of the test results) under the supervision of an experienced healthcare professional.
- Attend several practical screening sessions (person-to-person contact, outreach situations) or simulated situations at the official reference centre: pre- and post-test information settings (including receiving people from key populations, conducting interviews, sampling, reading the test results, accidental exposure, ...) . These sessions should also make it possible to gain a first-hand insight into the appropriate manner in which the test results should be delivered (pre- and post-counselling).

Upon completion of the training, the accredited training centre issues a training certificate (with accreditation).

About the Superior Health Council (SHC)

The Superior Health Council is a federal advisory body. Its secretariat is provided by the Federal Public Service Health, Food Chain Safety and Environment. It was founded in 1849 and provides scientific advisory reports on public health issues to the Ministers of Public Health and the Environment, their administration, and a few agencies. These advisory reports are drawn up on request or on the SHC's own initiative. The SHC aims at giving guidance to political decision-makers on public health matters. It does this on the basis of the most recent scientific knowledge.

Apart from its 25-member internal secretariat, the Council draws upon a vast network of over 500 experts (university professors, staff members of scientific institutions, stakeholders in the field, etc.), 300 of whom are appointed experts of the Council by Royal Decree. These experts meet in multidisciplinary working groups in order to write the advisory reports.

As an official body, the Superior Health Council takes the view that it is of key importance to guarantee that the scientific advisory reports it issues are neutral and impartial. In order to do so, it has provided itself with a structure, rules and procedures with which these requirements can be met efficiently at each stage of the coming into being of the advisory reports. The key stages in the latter process are: 1) the preliminary analysis of the request, 2) the appointing of the experts within the working groups, 3) the implementation of the procedures for managing potential conflicts of interest (based on the declaration of interest, the analysis of possible conflicts of interest, and a Committee on Professional Conduct) as well as the final endorsement of the advisory reports by the Board (ultimate decision-making body of the SHC, which consists of 40 members from the pool of appointed experts). This coherent set of procedures aims at allowing the SHC to issue advisory reports that are based on the highest level of scientific expertise available whilst maintaining all possible impartiality.

Once they have been endorsed by the Board, the advisory reports are sent to those who requested them as well as to the Minister of Public Health and are subsequently published on the SHC website (www.shc-belgium.be). Some of them are also communicated to the press and to specific target groups (healthcare professionals, universities, politicians, consumer organisations, etc.).

In order to receive notification about the activities and publications of the SHC, please contact: info.hgr-css@health.belgium.be.