

## **PUBLICATIE VAN DE HOGE GEZONDHEIDSRAAD nr 9224**

### **Gedecentraliseerde en gedemedealiseerde screening op HIV in België: antwoord op een adviesaanvraag van de volksgezondheidsoverheden.**

*Dit advies heeft tot doel om specifieke aanbevelingen te formuleren over de precieze omstandigheden waaronder gedecentraliseerde en gedemedealiseerde screening op HIV in België moet worden uitgevoerd. Deze zijn bestemd voor de Belgische volksgezondheidsoverheden, medische en niet-medische professionals, not-for-profit organisaties of verenigingen die betrokken zijn bij de preventie van SOA's/AIDS.*

juli 2015

### **1. INLEIDING EN VRAAGSTELLING**

Op 25 juni 2014 kreeg de Hoge Gezondheidsraad (HGR) een nieuwe adviesaanvraag van de vorige federale minister van Volksgezondheid "betreffende de context waarbinnen [...] gedecentraliseerde en gedemedealiseerde screening dient te gebeuren" (sic) in België).

De achtergrond en het kader van dit advies berusten op de meest recente aanbevelingen en richtlijnen van de WHO<sup>1</sup> en het ECDC<sup>2</sup> omtrent de voor HIV-testen gebruikte strategieën (vgl. hoofdstuk 4. Referenties) alsook het Belgisch "Nationaal HIV-plan", dat is voorgesteld in oktober 2013 en loopt tussen 2014 en 2019. In dit plan worden een reeks vereisten vastgelegd voor gedecentraliseerde en gedemedealiseerde teststrategieën. De definities voor de gedecentraliseerde en gedemedealiseerde HIV-teststrategieën waarnaar wordt verwezen in dit advies bevinden zich in hoofdstuk 3.2.

De informatie die moet worden verstrekt in het kader van een HIV-teststrategie omvat de volgende elementen: hoe de deelnemers te counsellen, waar de toegangspunten te vinden (d.w.z. plaatsen waar stalen worden afgenomen), welk soort testen worden gebruikt, en hoe de testuitslag mee te delen. Onder zijn "Principes van de strategie" vermeldt het Nationaal HIV-plan dat het testen op HIV een transversale aangelegenheid is (blz. 22 van de Nederlandse versie). Toch wenst de HGR bijzondere nadruk te leggen op het belang van de *linkage to care*, die een integraal onderdeel van de testprocedure moet zijn.

Betreffende de gedecentraliseerde en gedemedealiseerde testen worden in het HIV-plan drie specifieke actiepunten aangekaart:

- "Gedecentraliseerde screening en screening buiten de medische sfeer ondersteunen" ("Opsporing en toegang tot behandeling", punt 9, blz. 25 Nederlandse versie).
- "Een juridisch kader formuleren dat gedecentraliseerde screening en screening buiten de medische sfeer mogelijk moet maken" ("Opsporing en toegang tot behandeling", punt 10, blz. 25 Nederlandse versie).

<sup>1</sup> World Health Organization (Wereldgezondheidsorganisatie)

<sup>2</sup> European Centre for Disease Control and Prevention

- "Met de lokale ARC<sup>3</sup> opsporingsdiensten ontwikkelen die gevestigd zijn in de gemeenschap en een snelle en aangepaste toegang verzekeren tot diensten voor zorgverlening, behandeling en ondersteuning" (Opsporing en toegang tot behandeling, punt 15, blz. 25 Nederlandse versie).

De huidige state-of-the-art HIV-teststrategie is een gemedicaliseerde en gecentraliseerde strategie, d.w.z. een strategie die wordt uitgevoerd door een gezondheidswerker in een klinische omgeving. Deze *state-of-the-art* strategie gebruikt laboratoriumtesten (enzymimmunoassays, immunoblot) op bloedstalen en de uiteindelijke testresultaten worden meegedeeld tijdens een face-to-face consultatie bij een arts/gezondheidswerker.

Het is belangrijk te benadrukken dat deze HIV-teststrategie voor de meeste mensen (inclusief minderjarigen) nog steeds de voorkeur krijgt. Gedecentraliseerde en gedemedicaliseerde strategieën moeten enkel worden gebruikt voor mensen die met de huidige strategie tussen wal en schip zouden vallen. Zo staat het beschreven in het Belgisch Nationaal HIV-Plan van 2013<sup>4</sup> en de richtlijnen van het ECDC over HIV-testen van 2010 (zie hoofdstuk 4 Referenties). In het verslag van het ECDC kijken de auteurs naar verschillende manieren om de barrières ten overstaan van HIV-testen te overwinnen (op het niveau van het individu, dat van de zorgverlener, en op institutioneel niveau). Voorts komen ook strategieën aan bod om de afname van HIV-testen te verhogen, zoals de toestemmingsprocedure vereenvoudigen, alternatieven voor (pre- en post-test) counseling beschrijven, alternatieve HIV-testtechnologieën gebruiken, en de toegang tot zorgverlening verzekeren.

De laatste jaren werden een reeks programma's met alternatieven voor verschillende aspecten van de huidige *state-of-the-art* strategie ontwikkeld en pilot getest. Deze alternatieven omvatten het volgende: het verzamelen van stalen tijdens *outreach*-activiteiten, het gebruik van sneltesten voor HIV, het gebruik van speekselstalen (in plaats van bloedstalen), het meedelen van de resultaten van de oriëntatietesten per telefoon/sms/via het internet, en het betrekken van niet-medische professionals, die het HIV-testproces kunnen vergemakkelijken en er zelfs toe kunnen bijdragen. Elk van deze elementen zal in dit document uitvoerig worden besproken.

## 2. ADVIES

### Voorwoord

Het verzoek van de minister strookt niet met de bepalingen van het koninklijk besluit nr. 78 van 10 november 1967, dat "gedecentraliseerde en gedemedicaliseerde screening" verbiedt. De HGR adviseert dan ook de bevoegde overheden om de relevante wetgeving betreffende de uitoefening van de gezondheidszorgberoepen, met inbegrip van dit koninklijk besluit, aan te passen.

### Definities

Wanneer de voorwaarden worden beschreven waaronder "gedecentraliseerde en gedemedicaliseerde screening" moet worden uitgevoerd, is eerst en vooral een duidelijke definitie nodig van wat wordt verstaan onder de gebruikte termen. De betekenis ervan verschilt immers naar gelang van het in overweging genomen kader alsook van de beoogde doelstellingen (laboratorium, medisch kader (dokterspraktijk), externe omgeving, enz.). Om misverstanden te voorkomen, wordt in hoofdstuk 3.2 van dit advies een overzicht gegeven van de betekenissen waarin de HGR deze en andere rechtstreeks daarmee verbonden termen gebruikt.

---

<sup>3</sup>AIDS Referentiecentra

<sup>4</sup> MSM (mannen die seks hebben met mannen), migranten, intraveneuze druggebruikers, jongeren, sekswerkers, gedetineerden, enz.

De HGR is van oordeel dat de bevolking over dit onderwerp grondig moet worden ingelicht. Toch is er heel wat verwarring rond het gebruik van deze termen door dienstverleners, op het internet, door de industrie, enz. De Belgische volksgezondheidsinstanties moeten zich daarom rekenschap geven van de noodzaak om een duidelijke en officiële (wettelijke) omschrijving te geven van de verschillende beschikbare teststrategieën, alsook van alle termen die in verband daarmee worden gebruikt.

### Oriëntatietest

De HGR stelt voor om i.v.m. HIV-testprogramma's het neologisme "oriëntatietest" te gebruiken, dat het indicatief karakter van de resultaten weerspiegelt. Deze resultaten worden immers verkregen aan de hand van testen die zijn uitgevoerd op een wijze die niet in lijn is met *state-of-the-art* strategieën, zoals beschreven onder de definities (hoofdstuk 3.2).

Er moet worden opgemerkt dat de negatief voorspellende waarde voor sneltesten (op bloed) in de meeste beschikbare studies tussen 99,7% en 100% bedraagt en dat de positief voorspellende waarde (ook op bloed) varieert tussen 67% en 99,5% (gegevens beschikbaar voor populaties met een hoge seroprevalentie in Afrika). Enkel de sneltesten op bloed zijn gevalideerd.

### Implementatie en evaluatie

Een eerste vereiste is dat de pretest-fase van dergelijke screeningsprojecten moet worden gestandaardiseerd. Aangezien dit een proces is dat zowel de medische dimensie alsook de aspecten i.v.m. laboratoriumwerk en de hoogrisicogemeenschappen betreft, beveelt de HGR aan om een "stuurgroep" (met deskundigen en vertegenwoordigers van de ARL<sup>5</sup>, ARC, NGO's<sup>6</sup>, enz. in te stellen. Deze zou tot taak moeten hebben om te beoordelen in hoeverre een programma waarin gedecentraliseerde en gedemedicaliseerde screening wordt aangeboden door één van de daartoe bevoegde structuren, geschikt is.

Vervolgens moeten de gegevens binnen dezelfde, breed actieve structuur worden verzameld en verwerkt (*linkage to care*, opvolging ...) . Het huidige programma moet worden geharmoniseerd (geïntegreerde zorg). Deze overkoepelende aanpak maakt het inderdaad mogelijk om de kwaliteit van wat is geïmplementeerd te beoordelen. Momenteel is het Belgische Wetenschappelijk Instituut Volksgezondheid (WIV) de enige wetenschappelijke instelling die in staat is om deze epidemiologische gegevens te centraliseren en de uitwisseling van informatie met de relevante Europese structuren te verzekeren. De HGR geeft dan ook aan de bevoegde federale gezondheidsinstanties de raad om in deze zin te handelen, rekening houdend met de informatie en de voorstellen die hij heeft geformuleerd.

### Opleiding

Gezien de context waarin gedecentraliseerde en gedemedicaliseerde screening wordt uitgevoerd, is het noodzakelijk om inzicht te krijgen in het aldus bereikte kwaliteitsniveau. Hiervoor is het nodig om een kwaliteitsborgingssysteem voor gedecentraliseerde en gedemedicaliseerde screening op te zetten.

Om deze reden adviseert de HGR de Belgische volksgezondheidsinstanties om een specifiek voortgezet opleidingsprogramma voor de betrokkenen op te starten. Meer bepaald moet een dergelijke opleiding zich richten naar gezondheidswerkers, zoals gedefinieerd in de wetgeving, alsook naar vrijwilligers/werknemers die geen beroep in de gezondheidszorg in de juridische zin uitoefenen, maar die wel actief zijn in een preventieorganisatie of vereniging zonder winstoogmerk die psychosociale ondersteuning biedt aan de getroffen prioritaire doelgroepen en actief is in de preventie van SOA's<sup>7</sup>/AIDS<sup>8</sup> (en aanverwante medische kwesties) (zie hoofdstuk

<sup>5</sup> AIDS-referentielaboratoria

<sup>6</sup> Niet-gouvernementele organisatie

<sup>7</sup> Seksueel overdraagbare aandoeningen

<sup>8</sup> *Acquired immune deficiency syndrome*

3.4). Wat betreft het screenen op HIV/AIDS aan de hand van de oriëntatietest, moeten alle betrokkenen een specifieke opleiding over HIV-testen genieten. Deze opleiding moet worden gegeven door een medische structuur gespecialiseerd in HIV (in samenwerking met - of zelfs op initiatief van - andere structuren in verband met de prioritaire doelgroepen). Maar ze moeten ook een voortgezette opleiding afronden over HIV/AIDS-infectie die wordt aangeboden door dezelfde medische structuren. Voor het afleveren van een certificaat (met accreditatie) na voltooiing van het opleidingsprogramma is de gespecialiseerde medische structuur verantwoordelijk. In bijlage 2 van dit document bevindt zich ter informatie een eerste voorstel omtrent de inhoud van dit opleidingsprogramma (theoretisch en praktijkgedeelte).

### **Informatie**

Voor de "contactpunten gezondheidszorg" (zie hoofdstuk 3.4):

De HGR adviseert dat alvorens een programma met alternatieve HIV-teststrategieën wordt opgestart, een brochure ter beschikking wordt gesteld met daarin een uitvoerige beschrijving van het project. Deze brochure moet op zijn minst een hoofdstuk bevatten over de gebruikte methoden (kader, doelgroep, procedures voor het afnemen van de stalen, het uitvoeren van de tests, het meedelen van de resultaten, *counseling* en *linkage to care*). Bovendien moeten ook ethische kwesties worden aangekaart (en hoe daarmee wordt omgegaan), en moet uitleg worden gegeven over *data management* en vertrouwelijkheid.

Voor de deelnemers:

De HGR adviseert dat alvorens een programma met alternatieve HIV-teststrategieën wordt opgestart, de deelnemers gedetailleerde, schriftelijke informatie krijgen over de procedures, ethische kwesties, alsook over *data management* en vertrouwelijkheid. Zij moeten ook worden geïnformeerd over de beperkingen van dergelijke testen.

*Hoewel dit de Nederlandstalige versie is van het advies, zijn de delen discussie en uitwerking enkel beschikbaar in het Engels.*

**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.

### 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<sup>9</sup>-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.

---

<sup>9</sup> 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<sup>10</sup> and VL<sup>11</sup> 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

<sup>10</sup> cluster of differentiation 4 (cell surface molecules present on leukocytes)

<sup>11</sup> 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):
  - o GP's surgery (family doctor);
  - o Other medical facilities (emergency departments, gynaecological consultations, private laboratories, etc.);
  - o Outreach activities;
  - o Civil society organisations (NGOs or CBOs<sup>12</sup>);
  - o On-line tests;
  - o At home (self-tests).
- The sample that is collected (non-exhaustive list):
  - o Blood sample: whole blood, serum, plasma, dried blood spot, dried plasma spot, collected through venous puncture or finger prick;
  - o Oral fluid (saliva) sample.

---

<sup>12</sup> Community-based organisation



- The location at which the test is conducted:
  - o Clinical setting (see section 3.2 for definition);
  - o Civil society organisations;
  - o Laboratory;
  - o At home;
  - o During outreach activities.
- The timing and manner in which the test results are communicated (non-exhaustive list):
  - o On site (when using rapid tests);
  - o During a face-to-face consultation (with physician, trained counsellor, or peer);
  - o On-line communication: only by using state-of-the-art protection measures to secure the data (e.g. with a personal password);
  - o Communication over the telephone: only by using state-of-the-art protection measures to secure the data (e.g. with a personal password);
  - o 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:
  - o Refer to medicalised testing and provide information on financial implications;
  - o Ensure access to counselling services;
  - o Provide information on the window periods;
  - o 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 4<sup>th</sup> 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 4<sup>th</sup> 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:
  - o a highly accessible counselling strategy, where the programme participants can receive proper, individually tailored counselling from a trained volunteer, peer or healthcare professional;
  - o 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 4<sup>th</sup> 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 <sup>(\*)</sup>: appointed personnel providing medical services {*acte délégué - gedelegeerde handeling*):
  - o Physicians
  - o Pharmacists
  - o Specialists in medical biology (physicians or pharmacists, in Belgium)
  - o Midwives<sup>(\*)</sup>
  - o Nurses<sup>(\*)</sup>
  - o Clinical-biology laboratory technologists<sup>(\*)</sup>
- 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

- Belgian HIV National Plan 2014-2019, October 2013 (available in French, Dutch, German and English) <http://www.breach-hiv.be/media/docs/HIVPlan/NationalPlanEng.pdf>
- Belgium. Royal decree n°78 of November 10th 1967.  
[http://www.ejustice.just.fgov.be/cgi\\_loi/change\\_lg.pl?language=fr&la=F&table\\_name=loi&cn=1967111008](http://www.ejustice.just.fgov.be/cgi_loi/change_lg.pl?language=fr&la=F&table_name=loi&cn=1967111008) (also available in Dutch).
- British HIV Association. British Association for Sexual Health and HIV · British Infection Society. “UK National Guidelines for HIV Testing”. 2008.  
<http://www.bhiva.org/documents/guidelines/testing/glineshivtest08.pdf>
- CNS. Conseil national du sida (France). Rapport sur les autotests de dépistage de l'infection à VIH adopté par le Conseil National du Sida le 20 décembre 2012.  
[http://www.cns.sante.fr/IMG/pdf/2012-20-12\\_rap\\_fr\\_depistage.pdf](http://www.cns.sante.fr/IMG/pdf/2012-20-12_rap_fr_depistage.pdf)
- CNE. Comité consultatif national d'éthique pour les sciences de la vie et de la santé (France). Avis sur les problèmes éthiques posés par la commercialisation d'autotests de dépistage de l'infection VIH . Avis n°119. 21 février 2013.  
[http://www.ccne-ethique.fr/sites/default/files/publications/avis\\_119.pdf](http://www.ccne-ethique.fr/sites/default/files/publications/avis_119.pdf)
- Delaugerre C, Simon F. Les TROD : des outils pour le dépistage du VIH ? Feuillet de Biologie, 2012, vol. LIII, n°304, 9 p.
- ECDC. European Centre for Disease Prevention and Control. HIV testing: Increasing uptake and effectiveness in the European Union. Stockholm: ECDC; 2010.  
[http://ecdc.europa.eu/en/publications/Publications/101129\\_GUI\\_HIV\\_testing.pdf](http://ecdc.europa.eu/en/publications/Publications/101129_GUI_HIV_testing.pdf)
- France. Journal Officiel de la République Française. Arrêté du 9 novembre 2010 fixant les conditions de réalisation des tests rapides d'orientation diagnostique de l'infection à virus de l'immunodéficience humaine (VIH 1 et 2).  
<http://www.legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT000023093746&dateTexte&categorieLien=id>
- HAS. Haute Autorité de Santé (France). Dépistage de l'infection par le VIH – Stratégies et dispositif de dépistage. Argumentaire Oct 2008.  
[http://has-sante.fr/portail/upload/docs/application/pdf/2009-10/argumentaire\\_depistage\\_vih\\_volet\\_2\\_vfv\\_2009-10-21\\_16-49-13\\_375.pdf](http://has-sante.fr/portail/upload/docs/application/pdf/2009-10/argumentaire_depistage_vih_volet_2_vfv_2009-10-21_16-49-13_375.pdf)
- INAMI-RIZIV. Confidential report, 2014 (not published).
- NAM. National AIDS Manual. Aidsmap HIV & AIDS news. Rapid tests.  
<http://www.aidsmap.com/Rapid-tests/page/1323371/>
- Public Health England “HIV Testing and Self-Testing - Answers to frequently asked questions”, 2014.  
[http://www.champspublichealth.com/sites/default/files/media\\_library/HIV%20Testing%20and%20Self%20Testing%20Frequently%20Asked%20Questions%20April%202014.pdf](http://www.champspublichealth.com/sites/default/files/media_library/HIV%20Testing%20and%20Self%20Testing%20Frequently%20Asked%20Questions%20April%202014.pdf)
- SHC. Superior Health Council (Belgium). Advisory report nr. 5109. Recommandations du Conseil Supérieur de la Santé en matière de déchets médicaux (March 2005).



[http://www.health.belgium.be/eportal/Aboutus/relatedinstitutions/SuperiorHealthCouncil/publications/4388397\\_FR?ie2Term=5109&ie2section=9744](http://www.health.belgium.be/eportal/Aboutus/relatedinstitutions/SuperiorHealthCouncil/publications/4388397_FR?ie2Term=5109&ie2section=9744) (also available in Dutch).

- WHO (World Health Organization):

Guidance on provider-initiated HIV testing and counselling in health facilities. 2007  
[http://www.who.int/hiv/pub/guidelines/9789241595568\\_en.pdf](http://www.who.int/hiv/pub/guidelines/9789241595568_en.pdf)

Scaling up HIV testing and counseling in the WHO European Region as an essential component of efforts to achieve universal access to HIV prevention, treatment, care and support. 2010. [http://www.who.int/hiv/pub/vct/hiv\\_testing\\_counseling/en/](http://www.who.int/hiv/pub/vct/hiv_testing_counseling/en/)

Service delivery approaches to HIV testing and counselling (HTC) : a strategic HTC programme framework. 2012.  
[http://apps.who.int/iris/bitstream/10665/75206/1/9789241593877\\_eng.pdf](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/](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.

<b>BOTBOL-BAUM Mylène</b>	Biomedical ethics	UCL, HELESI & IRSS
<b>DEBLONDE Jessika</b>	Infectious diseases	WIV-ISP
<b>DELFORGE Marie-Luce</b>	Medical microbiology	ULB-Erasme, Laboratoire de Référence SIDA.
<b>DEMOL Jacques</b>	Psychology	ULB, CHU Brugmann
<b>DE MOL Patrick</b>	Medical microbiology, infection control during care	ULg, CHU Sart-Tilman
<b>DERDELINCKX Inge</b>	Internal medicine, infectious diseases, HIV/AIDS.	UZ Leuven, ARC Leuven
<b>FRANSEN Katrien</b>	Clinical sciences	ITG, Aids Referentielaboratorium
<b>GENNOTTE Anne-Françoise</b>	Infectious diseases	CHU, Saint-Pierre, Cetim
<b>GOFFARD Jean-Christophe</b>	infectious diseases, HIV.	CHU Erasme, Centre de référence SIDA.
<b>LEONARD Philippe</b>	Internal medicine, infectious diseases, HIV.	ULG, CHU. Centre de référence Sida
<b>LEQUARRE Françoise</b>	Infectious diseases, HIV.	CHU-ULg, Centre de Référence Sida
<b>MANIRANKUNDA Lazare</b>	Public health, HIV-SAM Project	ITG, HIV-SAM Project
<b>PLATTEAU Tom</b>	Clinical sciences, sexology	ITG, HIV-STD Clinic
<b>VAN LAETHEM Yves</b>	Infectiology, vaccinology, HIV.	Hôpital St-Pierre, Bruxelles
<b>VANDEKERCHOVE Linos</b>	Internal medicine, infectious diseases, Clinical HIV.	UZ Gent, HIV-referentiecentrum
<b>VAN GYSEGHEM Jean-Marc</b>	Information, Law & society	UNamur, CRIDS
<b>YOMBI Jean-Cyr</b>	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 <sup>13</sup>
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 <sup>4</sup> .

<sup>13</sup> French-speaking non-profit organisation <sup>4</sup> 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 4<sup>th</sup> 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](http://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](mailto:info.hgr-css@health.belgium.be).