International Journal of STD & AIDS
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Int J STD AIDS published online 22 April 2014
DOI: 10.1177/0956462414531244

The online version of this article can be found at:
http://std.sagepub.com/content/early/2014/04/22/0956462414531244

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INTERNATIONAL JOURNAL OF STD & AIDS

International Journal of STD & AIDS
0(0) 1–10

DOI: 10.1177/0956462414531244
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2014 European Guideline on HIV testing

Deniz Gökengin[1], Anna Maria Geretti[2], Josip Begovac[3], Adrian Palfreeman[4], Milena Stevanovic[5], Olga Tarasenko[6] and Keith Radcliffe[7]

Abstract

Testing for HIV is one of the cornerstones in the fight against HIV spread. The 2014 European Guideline on HIV Testing provides advice on testing for HIV infection in individuals aged 16 years and older who present to sexually transmitted infection, genito-urinary or dermato-venereology clinics across Europe. It may also be applied in other clinical settings where HIV testing is required, particularly in primary care settings. The aim of the guideline is to provide practical guidance to clinicians and laboratories that within these settings undertake HIV testing, and to indicate standards for best practice.

Keywords

HIV, AIDS, testing, guideline, Europe

Date received: 4 March 2014; accepted: 10 March 2014

Introduction

Testing for HIV is a procedure for the diagnosis or exclusion of HIV infection based on the detection of HIV-specific antibodies and/or viral proteins and/or viral RNA/DNA in an individual, usually from a blood sample. The guideline represents an updated version of the 2008 European Guideline for Testing for HIV infection.[1] The main purpose of this guideline is to provide advice on testing for HIV infection in individuals aged 16 years and older who present to sexually transmitted infection (STI), genito-urinary or dermato-venereology clinics across Europe. Its aim is to provide practical guidance to clinicians and laboratories that in these settings undertake HIV testing, and to indicate standards for best practice. The guideline may also be applied in other clinical settings where HIV testing is required, particularly in primary care settings, depending on the characteristics of those attending, the nature of the health-care institution, and the social and epidemiological context. Decisions to follow this guideline must be based on professional judgment, consideration of individual patient circumstances and available resources.

The 2008 European Guideline of Testing for HIV Infection was the starting basis for the present guideline.[1] The search strategy was described in Appendix 1. In addition, the following guidelines and reports were reviewed in detail:

- UK National 2008 Guidelines for HIV Testing produced by the British Association for Sexual Health and HIV (BASHH), British HIV Association (BHIVA) and British Infection Society (BIS),[2]

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NICE has accredited the process used by BASHH to produce its European guideline on HIV testing. Accreditation is valid for 5 years from 2014.
More information on accreditation can be viewed at www.nice.org.uk/accreditation

- Centers for Disease Control and Prevention (CDC) Revised Recommendations for HIV Testing of Adults, Adolescents, and Pregnant Women in Health-care Settings,[3]
- 2013 US Preventive Services Task Force Recommendations for Screening for HIV Infection,[4]
- The American College of Physicians Guidance Statement on Screening for HIV in Health Care Settings (2009),[5]
- HIV indicator conditions: guidance for implementing HIV testing in adults in healthcare settings,[6]
- UNAIDS and World Health Organization (WHO) Working Group on Global HIV/AIDS/STI Surveillance Guidelines for Using HIV Testing Technologies in Surveillance: Selection, Evaluation, and Implementation,[7]
- WHO Guidance on Provider-initiated HIV Testing and Counseling in Health Facilities,[8] and
- European Centre for Disease Prevention and Control. HIV testing: increasing uptake and effectiveness in the European Union. Stockholm: ECDC, 2010.[9]

The system used to grade the evidence and guidance recommendations is that published by the US Department of Health and Human Services Agency for Healthcare Research and Quality (www.ahrq.gov) (Appendix 2). These are indicated in bold type throughout the text, e.g. **(Ia, A)**.

Goals of HIV testing

The primary goals of HIV testing are to:

- Identify HIV-infected individuals as early as possible and immediately link them into appropriate medical management and care;
- Provide counselling for HIV-negative individuals at risk of HIV acquisition;
- Reduce HIV transmission to others from those infected; and
- Initiate partner notification and provide counselling, testing and referral to prevention services for partners of HIV-positive persons.

Benefits of HIV testing

Early knowledge of HIV infection has many benefits. Initiation of antiretroviral therapy (ART) before severe immunosuppression and onset of disease has been shown to dramatically improve life expectancy and quality of life indicating the need for testing asymptomatic, high-risk individuals including those attending STI clinics[10–14] **(Ib, A)**. Antiretroviral treatment also markedly decreases the risk of HIV transmission by reducing viral burden and consequently the infectivity of diagnosed individuals[15] **(Ia, B)**. Furthermore, diagnosed individuals significantly reduce sexual and needle-sharing risk behaviours, especially with uninfected partners to whom they have disclosed their HIV status[16–22] **(Ia, A)**.

Presentation to care at a late stage of HIV infection is common in Europe. According to the 2012 report from the European Center for Disease Prevention and Control (ECDC), 49% of HIV-infected persons presented with a CD4 cell count below 350 cells/mm^3 and 30% presented with less than 200 cells/mm^3.[23] This implies that low access and uptake of HIV testing is an important public health issue in Europe. As several "indicator" conditions have been identified as occurring more often in HIV-infected persons, a variety of clinical settings play an important role in earlier HIV diagnosis.[6] Some testing guidelines now recommend indicator condition-guided HIV testing.[2,24] Although data on HIV prevalence across different clinical conditions are still emerging[25] we endorse the adoption of the indicator disease strategy for HIV testing in health care settings in Europe.

When to consider HIV testing in STI clinics

HIV is predominantly an STI in most parts of Europe. We therefore recommend universal opt-out testing of all sexually active individuals that present for medical care in the following circumstances:

- All individuals who seek care in STI/genito-urinary/dermato-venereology clinics regardless of signs or symptoms of disease or risk factors for infection should be offered an HIV test, as part of the initial screening for STI **(Ia, B)**. It is recognized that in some settings such as dermatology clinics a targeted approach may be preferred; in such settings, however a low threshold for recommending HIV testing is encouraged **(IIIb)** and data show high rates of patient acceptability.[26]
- Individuals whose history suggests a high likelihood of being exposed to HIV such as:
  - individuals whose symptoms are compatible with acute retroviral illness or immunosuppression;
  - individuals who have a past or current history of STI;
  - individuals who have been the victims of sexual assault;
  - individuals who are known sexual contacts of HIV-infected patients;
  - injecting drug users with needle-sharing behaviour;

  - individuals who had sexual exposure in countries with a high HIV prevalence[27];
  - individuals who are sexual contacts of people at recognized risk of HIV infection (e.g. from HIV endemic countries);
  - individuals who received blood or other blood products before introduction of routine HIV screening (in most European countries this is before 1985);
  - individuals with any indicator condition for HIV infection[6];
- Any pregnant woman regardless of risk factors;
- Persons who voluntarily seek testing, especially if they have never been tested before.

HIV testing and counselling should not be restricted to newly presenting patients and all previously HIV-negative patients should be offered and be encouraged to have HIV testing following possible re-exposure[4,28] **(Grade A)**. The optimal frequency of testing for those at ongoing risk is unknown due to lack of data, although every 12 months seems reasonable unless specific aspects of risk behaviour warrant more frequent testing (e.g. every 3–4 months) **(IV, C)**. Testing frequency should be based in part on the level of risk and requires a dialogue between the provider and the patient, which will include test history and any risk behaviours. Individuals with ongoing risk exposures should be counselled about risk reduction strategies **(IV, C)**.

Pre-test assessment

The HIV pre-test assessment should be pragmatic and patient-centred and be tailored for the individual patient.

The key element is obtaining informed consent to the test.[2] In addition, the initial evaluation should usually assess the likely window period (the time from possible exposure to the HIV test becoming positive) and whether repeat testing should be advised, and describe how and when the test result will be given **(IV, C)**.

Depending on circumstance, other components of pre-test assessment may include:

- Provide information on the benefits of HIV testing including the health benefits of early diagnosis and treatment, and the opportunity to reduce risk behaviour and risk of transmission to sexual partners or infants[8] **(IV, C);**
- Obtain a full sexual history and history of other types of risk behaviour (including date of last risk activity);
- Obtain HIV testing history (including the time, setting and reason of prior testing);
- Ensure knowledge of condom use and include a practical demonstration if needed. If appropriate, discuss risk reduction and the need for referral to other services, e.g. drug dependency treatment, support schemes, needle exchange programmes, etc.;
- Offer testing for other STIs;
- Offer post-exposure prophylaxis after sexual exposure (PEPSE) if indicated and available, in agreement with national policy. Detailed information on PEPSE can be found on the BHIVA website (http://www.bhiva.org/PEPSE.aspx);
- Give an opportunity to ask questions and answer them clearly; give more in depth information if required;
- Advice the patient to adopt safe sex behaviours and to follow national blood donation policies until the testing process is over.

Informed consent

- Verbal communication is usually sufficient for obtaining informed consent **(III, B)**. Obtaining written consent is a barrier to HIV testing and testing rates increase if testing requires only oral consent.[29]
- If a patient declines or defers HIV testing, this decision should be documented in the medical record. The reasons why they have made that choice should be explored to ensure that these are not due to incorrect beliefs about the virus or the consequences of testing **(IV, C)**.
- Declining an HIV test should not result in reduced quality or denial of services that do not depend on knowledge of HIV status[8] **(IV, C)**.

An information leaflet about HIV testing can provide or replace much of the information needed prior to obtaining informed consent, and is effective in many settings[30] **(III, B)**. The information leaflet should be prepared in an easy to understand and informative way, and be available in the languages commonly encountered in populations within the service.[8]

Special considerations apply in the case of adolescents who are below the legal age of consent. The pre-test discussion should be adapted to the patient's age, developmental stage and literacy level.[8] Since the legal framework, including the age of consent for sexual intercourse and offering testing and treatment services to adolescents varies between countries, relevant national guidelines should be consulted. If a national guideline is not available, advice is available from recent WHO/UNAIDS Guidance on provider-initiated testing and counselling in health facilities.[8]

Testing without informed consent

Where a patient is unable to give informed consent for HIV testing due to physical or mental incapacity – for example, if critically ill and unconscious – then HIV testing might be indicated to help diagnose the cause of the illness in the patient's best interests. In all cases where HIV testing is performed without informed consent, the health-care provider must be able to justify their actions and must take into consideration national legal and regulatory frameworks, guidance from national professional bodies and consensus opinion from experienced colleagues.[2]

Confidentiality

Individuals undergoing HIV testing should be informed that testing and test results will usually remain confidential.[1,2] However, individuals should also be advised that confidentiality is not absolute and that health-care providers may be legally bound to disclose HIV status information in exceptional circumstances.[2] It is recommended that this information is included in an information leaflet where possible **(IV, C)**. The use of a number or a false name may be an option where available for individuals who decline HIV testing due to concerns about confidentiality[1] **(IV, C)**.

Samples

- Venous blood is the preferred specimen for HIV testing **(IIa, B)**;
- Samples other than venous blood, such as finger-prick blood or oral fluid may be used for HIV testing in specific circumstances and subjected to rigorous training and quality assurance.[7]

Recommendations for the laboratory

HIV screening and confirmatory tests

Screening serology test

- Fourth generation screening assays that simultaneously test for anti-HIV antibodies and p24 antigen are recommended.[31] Assays available in Europe have excellent sensitivities (99.78–100%) and specificities (99.5–99.93%).[32,33]

Confirmation of reactive serology results

- Reactive screening test results should be confirmed in a laboratory with experience in HIV confirmation **(IV, C);**
- Confirmatory algorithms vary. Generally, they include at least one additional antibody or antibody/antigen serology test that employs a different platform from the initial screening test[34] **(III, B)**. An antibody test is also used to differentiate between HIV types. The final laboratory report must clearly indicate whether the patient has an HIV-1, HIV-2 or dual infection **(IV, C)**.
- Repeat serology testing of a second sample is recommended to rule out mislabelling and confirm patient identity **(IV, C)**. It may be replaced by testing a plasma sample for HIV-1 RNA, provided the viral load is >1000 copies/mL. In patients with a lower or undetectable viral load, a second serum sample should be collected for repeat serological testing[35] **(IV, C)**.

Confirmation of indeterminate/equivocal screening results. Indeterminate results may reflect false reactivity or early HIV infection. All patients with an initial indeterminate result should undergo repeat testing 1–2 weeks later. False negative reactivity generally clears over follow-up, although several tests may be required. Where there is strong suspicion of recent infection, HIV-1 RNA (or in some cases p24 antigen) may be tested **(IV, C)**.

Recent HIV infection. Nucleic acid amplification tests (NAAT), typically plasma HIV-1 RNA testing, are not recommended for initial HIV screening because while they offer a marginal advantage over fourth generation screening assays in detecting recent HIV infection, they are not licensed for diagnostic use and may give false-positive results[36–38] **(IV, C)**.

HIV-1 RNA testing is indicated in patients with suspected primary HIV infection who show negative or indeterminate serology results **(IIb)**; if HIV-1 RNA is detected, infection should be confirmed by demonstrating seroconversion in a sample collected 1–2 weeks later. Low HIV-1 RNA values (<1000 copies/mL) should be interpreted with caution and not considered as indicative of infection in the absence of further evidence **(IIb)**. In settings where NAAT is not widely available or affordable, or in circumstances where there is no suspicion of a recent HIV infection, NAAT is replaced by fourth generation screening test repeated 1–2 weeks later **(IV, C)**.

Quality control

- All HIV testing and confirmation should be done in accredited laboratories under strict quality control **(IV, C)**.

- Where a national laboratory accreditation scheme is not available, testing should be undertaken only using approved (i.e. Conformité Européenne [CE]) tests under a strict quality assurance programme; quality assurance results should be made available for inspection where required **(IV, C)**.
- Point of care testing (POCT) services (see below) should be subject to the same strict quality assurance principals as practiced by accredited laboratories **(IV, C)**. This includes using standard operating procedures (SOPs), regular use of external controls and an external quality assessment process. Regular on-site audits should be performed to observe if SOPs are followed, records are maintained, adequate training is provided, internal and external quality standards are used and selected samples are validated in a reference laboratory.[39–41]
- Local rules and regulations should be followed for storage of plasma/serum samples **(IV, C)**.
- Laboratories should provide their latest external quality control scores to their users upon request **(IV, C)**.

Interpreting HIV test results

The health-care provider should be aware of

- the HIV testing algorithm used in their laboratory;
- the HIV screening test (third or fourth generation) used in their laboratory;
- capability of their laboratory to distinguish between HIV-1 and HIV-2 infections.

Interpreting negative HIV test results

- Individuals whose specimens test negative on the initial HIV screening should be considered non-infected unless the patient presents with symptoms of primary HIV infection or has a history of recent ($\leq$6 weeks for fourth generation assays, $\leq$12 weeks for other assays) high-risk exposure **(IV, C)**. In the case of recent exposure, the tests should be repeated at 6 weeks to 12 weeks (according to the test to be used) from the time of exposure[31,36,42] **(IIb, B)**.
- Individuals with a high-risk exposure to HIV should not be fully reassured until the test process is completed[43] **(IV, C)**.
- When using fourth generation assays, individuals who have a negative screening test after 6 weeks of exposure may be recalled for a follow-up in specific circumstances, e.g. if post-exposure prophylaxis (PEP) was given for any reason (e.g. occupational or sexual exposure), with patients who are very anxious and seek further reassurance, where there is impaired ability to develop antibodies and where there is microbiologically proven simultaneous acute infection with another viral pathogen, such as human cytomegalovirus or hepatitis C virus.[2,44–46] In this case, the final testing time may be 12 weeks after exposure **(IV, C)**.
- For individuals presenting for PEP in the occupational setting, local professional regulations often recommend that HIV testing is postponed, and that a baseline venous blood sample should be stored at start of prophylaxis for retrospective testing in case follow-up testing is positive. Patients presenting for PEPSE however should be tested at the start of PEPSE. Due to reduced sensitivity, rapid HIV tests are not recommended as the sole mode of HIV testing in the context of PEP/PEPSE **(II, B)**.
- If a patient presents with clinical symptoms suggestive of HIV infection or AIDS and the HIV screening tests are repeatedly negative, then referral of the specimen to a specialized laboratory for analysis using alternative tests to exclude uncommon HIV strains is recommended **(IV, C)**.

Interpreting positive HIV test results

- A person should not be informed that he/she is HIV-positive based on an initial result of screening tests alone without a confirmatory test **(IV, C)**.
- Attention should be paid whether HIV-1 or HIV-2 (or both) has been diagnosed as it has important prognostic and treatment implications.

Interpreting indeterminate and unconfirmed HIV test results

HIV screening tests occasionally produce indeterminate or weakly reactive results that usually do not prove to be consistent with HIV infection.

- In cases where the initial reactive screening test cannot be confirmed, the result is reported as 'indeterminate' and a second blood sample should be requested **(IV, C)**. The first and second blood sample should be separated by at least one week.[2]
- An indeterminate screening test may indicate a possibility of recent infection. The best strategy in this situation is to obtain a follow-up specimen one week later for repeat testing **(IV, C)**. If on the follow-up sample the fourth generation test is clearly positive then a diagnosis of recent seroconversion can be made. Alternatively, where there are other

indications of a possible recent infection, the initial specimen can be tested for HIV-1 RNA (or in some cases p24 antigen) to diagnose early infection.[46,47] In all cases seroconversion should be confirmed on a follow-up specimen **(IV, C)**.
- Weakly reactive screening results that do not become more strongly reactive and cannot be confirmed on a subsequent appropriately timed sample are highly likely to indicate a non-specific reaction, i.e. false-positive result **(IV, C)**.

Point-of-care testing

Rapid, point-of-care tests facilitate access to HIV testing and ensure results are returned and are acted upon immediately. It is recommended that health-care providers familiarize themselves with the performance characteristics of the test adopted as these inform use and counselling **(III, B)**. Health-care providers should be aware that rapid HIV tests (including combined antibody/antigen tests) offer reduced sensitivity relative to laboratory-based tests and may therefore give false negative results in early HIV infection.[39,40,48–51] Reduced sensitivity has also been reported in advanced disease/AIDS.[52] In addition, as with all tests, the positive predictive value of a reactive test is reduced in low prevalence settings meaning that false positive results will occur to a different extent depending on the setting and population undergoing screening.[53]

Point of care tests that use sample types other than blood, such as oral fluid, may be subject to more variation in assay performance and sensitivity.[54] Obtaining a blood sample for laboratory testing is recommended in all patients with reactive or indeterminate results and in patients with a negative test if recent infection is suspected **(II, B)**.

Sites using POCTs should be overseen by the local laboratory and have a robust quality assurance programme[39,48] **(III, B)**.

Self-testing for HIV[55] – a procedure in which all stages of the HIV test take place outside the clinical setting and without the direction of trained personnel – is only recommended where validated tests are available with appropriate support and access to clinical care. It may become an option in the future for persons seeking anonymity and privacy, if evidence substantiates the practice[56–58] **(IV, C)**.

Post-test issues

Health-care providers should take care that the HIV test result and its delivery should remain confidential **(IV, C)**.

Post-test discussion for individuals who are negative

- Face-to-face post-test discussion is generally preferred for providing results, but alternative methods, such as telephone, letter or texting, may be appropriate in some instances **(IV, C)**. If alternative methods are used a standard procedure should be developed to ensure that the information is received by the tested individual **(IV, C)**.
- Discuss the window period and address the need for a repeated test in those with high-risk behaviour within the last 6–12 weeks (according to the test used).
- Encourage safe sex behaviour, particularly addressing behaviour change regarding unsafe sex or the maintenance of safer sexual practices; provide and demonstrate how to use condoms if necessary.
- Use the opportunity to refer persons with particular high-risk behaviours to HIV and other prevention services, e.g. drug-dependency treatment, support schemes, needle exchange programmes, etc.

Post-test discussion for individuals with inconclusive test results

- Post-test discussion for individuals with inconclusive test results should be done face-to-face whenever possible **(IV, C)**.
- An explanation should be provided on the significance and possible reasons for an inconclusive HIV test result.
- The nature of the additional tests that are required to resolve the inconclusive result should be explained.
- The importance of ongoing follow-up until the inconclusive result is resolved should be stressed.
- Discuss safer sex and safe drug-use behaviour until the indeterminate result is resolved.
- For persons reporting high-risk behaviour, discuss the possibility of acute HIV infection and consider additional NAAT or HIV-1 p24 antigen testing, particularly for pregnant women who have not been tested previously.

Post-test discussion for individuals who are positive

HIV-positive results should be given in a confidential environment and in a clear and direct manner.[1] Patients are often very distressed when first informed about a positive HIV test result. They are faced with major adaptive challenges, such as accepting to live with a chronic condition, being subject to intense stigma and

discrimination and developing and adopting strategies for maintaining physical and emotional health.[1,59] Appropriate support should be available on site or through referral to address the behavioural, psychosocial and medical implications of HIV infection. The following issues should be covered.[1]

- Inform the patient straightforwardly that the HIV test was positive and make sure that the patient has understood the implications of a positive test.
- Plan for repeat serology or HIV-1 RNA testing of a second sample to rule out mislabelling and to confirm patient identity.
- Discuss the importance of partner notification.
- Address the question of whom the patient wants to inform, now and later, e.g. partner(s), friends, family.
- Discuss what will happen next and clarify whether the client wants to talk further at this stage or not. Experience has shown that even when the patient expected a positive result, there is still a powerful emotional reaction. Hence, it may be wise to postpone some of the information giving to subsequent consultations.[1]
- Schedule a new consultation in the near future, e.g. next day.
- Inform them that treatment is available and discuss current treatment options. Discuss antiretroviral drugs and emphasize their ability to control HIV disease effectively. Inform them that mortality rates for HIV-infected persons have become much closer to general mortality rates since the introduction of ART.[60]
- Assess the need for psychological support or contact with other services, e.g. drug-dependency and refer as necessary.
- Discuss prevention methods such as safe sex, use of condoms, not sharing needles, etc. to reduce transmission to others and transmission of other STIs to the patient.
- Encourage partner notification for providing testing and medical care if needed for the partner. Regarding the seropositive woman, the following should be included in the counselling at an early stage.[1]
- Discuss the implications for possible future pregnancy such as the risks for the child and the need for ART during pregnancy. Inform that antiretroviral treatment if administered to women during pregnancy and to the newborn child for a short period can significantly reduce this risk of mother-to-child transmission.[61,62]
- If already pregnant, discuss the implications. Further guidance should be sought from relevant national guidelines or, if not available, from the CDC (www.cdc.gov/hiv) or the BHIVA (www.bhiva.org).

Following a positive HIV diagnosis, a newly diagnosed individual should be immediately referred to an appropriate specialist HIV treatment centre for further management and care. However, it should be stressed that after HIV diagnosis it is important to offer not only continuous monitoring of viral and immunological parameters for HIV infection, but also regular, comprehensive and easily accessible monitoring of other STIs and repeated sexual risk reduction counselling in a context of sympathetic, non-judgemental sexual history-taking.[63]

Non-attendance for positive results

- An agreed recall process following failure of a patient to return for an HIV-positive result should be established and contact options should be discussed with the patient at the first testing visit **(IV, C)**.
- Attempts should be made to contact the patient if they test positive and fail to collect the result **(IV, C)**; this may include making telephone calls, sending emails or text messages, sending letters or making home visits.

Voluntary disclosure, partner notification and contact tracing

Partner notification or partner referral is a cornerstone of STI programs worldwide.[64] The rationale for partner notification is that early diagnosis and treatment of HIV infection may significantly reduce morbidity and mortality, and provides the opportunity to reduce high-risk behaviour.[1] All patients should be strongly advised to disclose their HIV infection status to their regular, previous and new sexual or injecting partner(s) and those at risk to be tested for HIV[1,59] **(IV, C)**. In addition, testing of all children of HIV-positive women is recommended as HIV transmission has been documented from breastfeeding from mothers who acquired their infection postnatally, and vertically acquired HIV infection can present in adolescence **(IV, C)**. Further information can be found in the 2013 European Guideline on the Management of Partners of Persons with Sexually Transmitted Infections at www.iusti.org.

Acknowledgement

The authors would like to thank to Willem van der Meijden, Anastasia Pharris and Jonathan Ross the contributing organizations (Appendix 3) and the members of the

European STI Guidelines Editorial Board (Appendix 4) for their contributions.

Conflict of interest

The authors declare no conflict of interest.

Funding

This research received no specific grant from any funding agency in the public, commercial, or not-for-profit sectors.

References

1. Poljak M, Smit E and Ross J. 2008 European guideline on HIV testing. *Int J STD AIDS* 2009; 20: 77–83.
2. British HIV Association. British Association of Sexual Health and HIV, British Infection Society (2008) UK National Guidelines for HIV Testing 2008. http://www.bhiva.org/HIVTesting2008.aspx (accessed 25 May 2013).
3. Branson BM, Handsfield HH, Lampe MA, et al.; Centers for Disease Control and Prevention (CDC). Revised recommendations for HIV testing of adults, adolescents, and pregnant women in health-care settings. *MMWR Recomm Rep* 2006; 55(RR-14): 1–17; quiz CE1-4.
4. US Preventive Services Task force Recommendations for Screening for HIV Infection. http://www.uspreventiveservicestaskforce.org/uspstf/uspshivi.htm (accessed 25 May 2013).
5. Qaseem A, Snow V, Shekelle P, et al. Clinical Efficacy Assessment Subcommittee, American College of Physicians. Screening for HIV in health care settings: a guidance statement from the American College of Physicians and HIV Medicine Association. *Ann Intern Med* 2009; 150(2): 125–131.
6. HIV Indicator Conditions: Guidance for Implementing HIV testing in Adults in Healthcare Settings. http://issuu.com/kandrup/docs/chip_guidance?e=4233206/1998749 (2012, accessed 27 June 2013).
7. UNAIDS WHO Working Group on Global HIV/AIDS/STI Surveillance Guidelines for Using HIV Testing Technologies in Surveillance: Selection, Evaluation, and Implementation 2001. http://www.unaids.org/en/media/unaids/contentassets/dataimport/publications/irc-pub02/jc602-hivsurvguidel_en.pdf (accessed 25 May 2013).
8. World Health Organization Guidance on provider-initiated HIV testing and counseling in health facilities. http://whqlibdoc.who.int/publications/2007/9789241595568_eng.pdf (accessed 25 May 2013).
9. European Centre for Disease Prevention and Control. *HIV testing: increasing uptake and effectiveness in the European Union*. Stockholm: ECDC, 2010. http://www.ecdc.europa.eu/en/publications/Publications/101129_GUI_HIV_testing.pdf (accessed 15 February 2014).
10. Kitahata MM, Gange SJ, Abraham AG, et al. Effect of early versus deferred antiretroviral therapy for HIV on survival. *N Engl J Med* 2009; 360: 1815–1826.
11. May M, Gompels M, Delpech V, et al. Impact of late diagnosis and treatment on life expectancy in people with HIV-1: UK Collaborative HIV Cohort (UK CHIC) Study. *BMJ* 2011; 343: d6016.
12. Johnson LF, Nakagawa F, May M, et al. Updates of lifetime costs of care and quality of life estimates for HIV-infected persons in the United States: late versus early diagnosis and entry into care. *J Acquir Immune Defic Syndr*. Epub ahead of print 22 April 2013. PMID: 23615000.
13. May M, Gompels M and Sabin C. Life expectancy of HIV-1-positive individuals approaches normal, conditional on response to antiretroviral therapy: UK collaborative HIV cohort study. *J Int AIDS Soc* 2012; 15(Suppl 4): 18078.
14. Soria A and Lazzarin A. Antiretroviral treatment strategies and immune reconstitution in treatment-naive HIV-infected patients with advanced disease. *J Acquir Immune Defic Syndr* 2007; 46: S19–S30.
15. Cohen MS, Chen YQ, McCauley M, et al. Prevention of HIV-1 infection with early antiretroviral therapy. *N Engl J Med* 2011; 365: 493–505.
16. Desenclos J-C, Papaevangelou G and Ancelle-Park R. Knowledge of HIV serostatus and preventive behaviour among European injecting drug users. *AIDS* 1993; 7: 1371–1377.
17. Kamb ML, Fishbein M, Douglas JM Jr, et al. Efficacy of risk-reduction counseling to prevent human immunodeficiency virus and sexually transmitted diseases: a randomized controlled trial. *JAMA* 1998; 280: 1161–1167.
18. Gibson DR, Lovelle-Drache J, Young M, et al. Effectiveness of brief counseling in reducing HIV risk behavior in injecting drug users: final results of randomized trials of counseling with and without HIV testing. *AIDS Behav* 1999; 3: 3–12.
19. Allen S, Meinzen-Derr J, Kautzman M, et al. Sexual behavior of HIV discordant couples after HIV counseling and testing. *AIDS* 2003; 17: 733–740.
20. Crepaz N, Lyles CM, Wolitski RJ, et al. Do prevention interventions reduce HIV risk behaviours among people living with HIV? A meta-analytic review of controlled trials. *AIDS* 2006; 20: 143–157.
21. Marks G, Crepaz N, Senterfitt JW, et al. Meta-analysis of high-risk sexual behavior in persons aware and unaware they are infected with HIV in the United States: implications of HIV prevention programs. *J Acquire Immune Defic Syndr* 2005; 39: 446–453.
22. Marks G, Crepaz N and Janssen RS. Estimating sexual transmission of HIV from persons aware and unaware that they are infected with the virus in the USA. *AIDS* 2006; 20: 1447–1450.
23. European Centre for Disease Prevention and Control/WHO Regional Office for Europe. *HIV/AIDS surveillance in Europe 2012*. Stockholm: European Centre for Disease Prevention and Control, 2013. http://www.ecdc.europa.eu/en/publications/Publications/hiv-aids-surveillance-report-2012-20131127.pdf (accessed 15 February 2014).
24. 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 (accessed 27 June 2013).
25. Sullivan AK, Raben D, Reekie J, et al. Feasibility and effectiveness of indicator condition-guided testing for HIV: results from HIDES I (HIV indicator diseases across Europe study). *PLoS One* 2013; 8(1): e52845.
26. Rayment M, Thornton A, Mandalia S, et al. HIV testing in non-traditional settings–the HINTS study: a multicentre observational study of feasibility and acceptability. *PLoS One* 2012; 7(6): e39530.
27. Data on the size of the HIV/AIDS epidemic: prevalence of HIV among adults aged 15 to 49 (%) by country. http://apps.who.int/gho/data/node.main.562?lang=en (accessed 18 February 2014).
28. Balaji AB, Bowles KE, Le BC, et al. NHBS Study Group. High HIV incidence and prevalence and associated factors among young MSM, 2008. *AIDS* 2013; 27(2): 269–278.
29. Charu L, Zetola NM, Klausner JD, et al. Association between rates of HIV testing and elimination of written consents in San Francisco. *JAMA* 2007; 297: 1061–1062.
30. Rogstad K, Bramham L, Lowbury R, et al. The use of a leaflet to replace verbal pretest discussion for HIV: effects and acceptability. *Sex Transm Infect* 2003; 79: 243–245.
31. Fiebig EW, Wright DJ, Rawal BD, et al. Dynamics of HIV viremia and antibody seroconversion in plasma donors: implications for diagnosis and staging of primary HIV infection. *AIDS* 2003; 17: 1871–1879.
32. Parry JV, Mortimer PP, Perry KR, et al. Towards error-free HIV diagnosis: guidelines on laboratory practice. *Commun Dis Public Health* 2003; 6: 334–350.
33. Perry KR, Ramskill S, Eglin R, et al. Improvement in the performance of HIV screening kits. *Transfus Med* 2008; 18: 228–240.
34. Joint United Nations Programme on HIV/AIDS (UNAIDS)-WHO. Revised recommendations for the selection and use of HIV antibody tests. *Wkly Epidemiol Rec* 1997; 72: 81–88.
35. Pillay D, Geretti AM and Weiss R. HIV. In: *Principles and practice of clinical virology*. 6th ed. Wiley, 2008.
36. Rich JD, Merriman NA, Mylonakis E, et al. Misdiagnosis of HIV infection by HIV-1 plasma viral load testing: a case series. *Ann Intern Med* 1999; 130: 37–39.
37. Sherman GG, Cooper PA, Coovadia AH, et al. Polymerase chain reaction for diagnosis of human immunodeficiency virus infection in infancy in low resource settings. *Pediatr Infect Dis J* 2005; 24: 993–997.
38. Marinovich A, Narlieva M, Bashir M, et al. False-positive result from a Bayer Versant human immunodeficiency virus type 1 branched-DNA viral load assay, with a possible role for light leakage after inadequate maintenance of the analyzer. *J Clin Microbiol* 2006; 4: 4288–4289.
39. World Health Organization. Rapid HIV Tests: Guidelines for Use in HIV Testing and Counselling Services in Resource-Constrained Settings. 2004. http://www.emro.who.int/aiecf/web28.pdf (accessed 14 October 2007).
40. Greenwald JL, Burstein GR, Pincus J, et al. A rapid review of rapid HIV antibody tests. *Curr Infect Dis Rep* 2006; 8: 125–131.
41. Wesolowski LG, MacKellar DA, Facente SN, et al. Post-marketing surveillance of OraQuick whole blood and oral fluid rapid HIV testing. *AIDS* 2006; 20: 1661–1666.
42. Ananworanich J, Fletcher JL, Pinyakorn S, et al. A novel acute HIV infection staging system based on 4th generation immunoassay. *Retrovirology* 2013; 10: 56.
43. Lindbäck S, Thorstensson R, Karlsson AC, et al. Diagnosis of primary HIV-1 infection and duration of follow-up after HIV exposure. Karolinska Institute Primary HIV Infection Study Group. *AIDS* 2000; 14: 2333–2339.
44. Ridzon R, Gallagher K, Ciesielski C, et al. Simultaneous transmission of human immunodeficiency virus and hepatic C virus from a needlestick injury. *N Engl J Med* 1997; 336: 919–922.
45. Young TN, Arens FJ, Kennedy GE, et al. Antiretroviral post-exposure prophylaxis (PEP) for occupational HIV exposure. *Cochrane Database Syst Rev* 2007; 24: CD002835.
46. Terzi R, Niero F, Iemoli E, et al. Late HIV seroconversion after non-occupational postexposure prophylaxis against HIV with concomitant hepatitis C virus seroconversion. *AIDS* 2007; 21(2): 262–263.
47. Hecht FM, Busch MP, Rawal B, et al. Use of laboratory tests and clinical symptoms for identification of primary HIV infection. *AIDS* 2002; 16: 1119–1129.
48. Centers for Disease Control and Prevention. Quality Assurance Guidelines for Testing Using Rapid HIV Antibody Tests Waived Under the Clinical Laboratory Improvement Amendments of 1988. 2007. www.cdc.gov/hiv/topics/testing/resources/guidelines/pdf/QA_Guidlines.pdf (accessed 27 June 2013).
49. Chetty V, Moodley D and Chuturgoon A. Evaluation of a 4th generation rapid HIV test for earlier and reliable detection of HIV infection in pregnancy. *J Clin Virol* 2012; 54(2): 180–184.
50. Faraoni S, Rocchetti A, Gotta F, et al. Evaluation of a rapid antigen and antibody combination test in acute HIV infection. *J Clin Virol* 2013; 57(1): 84–87.
51. Brauer M, De Villiers JC and Mayaphi SH. Evaluation of the Determine™ fourth generation HIV rapid assay. *J Virol Methods* 2013; 189(1): 180–183.
52. Brown P, Merline JR, Levine D, et al. Repeatedly false-negative rapid HIV test results in a patient with undiagnosed advanced AIDS. *Ann Intern Med* 2008; 149: 71–72.
53. Taegtmeyer M, MacPherson P, Jones K, et al. Programmatic evaluation of a combined antigen and antibody test for rapid HIV diagnosis in a community and sexual health clinic screening programme. *PLoS One* 2011; 6(11): e28019.
54. Pavie J, Rachline A, Loze B, et al. Sensitivity of five rapid HIV tests on oral fluid or finger-stick whole blood: a real-time comparison in a healthcare setting. *PLoS One* 2010; 5(7): e11581.
55. Frith L. HIV self-testing: a time to revise current policy. *Lancet* 2007; 369: 243–245.

56. Katz DA, Golden MR and Stekler JD. Use of a home-use test to diagnose HIV infection in a sex partner: a case report. *BMC Res Notes* 2012; 5: 440.
57. Ng OT, Chow AL, Lee VJ, et al. Accuracy and user-acceptability of HIV self-testing using an oral fluid-based HIV rapid test. *PLoS One* 2012; 7(9): e45168.
58. Pant Pai N, Sharma J, Shivkumar S, et al. Supervised and unsupervised self-testing for HIV in high- and low-risk populations: a systematic review. *PLoS Med* 2013; 10(4): e1001414.
59. Workowski KA and Berman S. Sexually transmitted diseases treatment guidelines 2010. *MMWR* 2010; 59(RR12): 1–110.
60. Bhaskaran K, Hamouda O, Sannes M, et al. Changes in the risk of death after HIV seroconversion compared with mortality in the general population. *JAMA* 2008; 300: 51–59.
61. Fowler MG, Lampe MA, Jamieson DJ, et al. Reducing the risk of mother-to-child human immunodeficiency virus transmission: past successes, current progress and challenges, and future directions. *Am J Obstet Gynecol* 2007; 197: S3–S9.
62. Suksomboon N, Poolsup N and Ket-Aim S. Systematic review of the efficacy of antiretroviral therapies for reducing the risk of mother-to-child transmission of HIV infection. *J Clin Pharm Ther* 2007; 32: 293–311.
63. Marcus U, Bremer V, Hamouda O, et al. Understanding recent increases in the incidence of sexually transmitted infections in men having sex with men: changes in risk behavior from risk avoidance to risk reduction. *Sex Transm Dis* 2006; 33: 11–17.
64. Gorbach PM, Aral SO, Celum C, et al. To notify or not to notify: STD patients' perspectives of partner notification in Seattle. *Sex Transm Dis* 2000; 27: 193–200.

Appendix 1

Search strategy

Evidence for this guideline was provided by review of the Medline/Pubmed, Embase, Google, Cochrane Library and relevant guidelines up to March 2013. A Medline/Pubmed and Embase and Cochrane Library search Cochrane Database of Systematic Reviews, Database of Abstracts of Reviews of Effects and Cochrane Central Register of Controlled Trials was carried out from January 2013 to March 2013, looking for the following terms in the title or abstract: 'HIV testing', 'HIV guideline(s)' and 'recommendation(s)'; 2337 citations were identified. For some specific recommendations, additional Medline/Pubmed search was performed when necessary. Google scholar search was performed in June 2013 with the search term 'HIV testing guideline(s)' and all relevant documents of the first 150 search results were reviewed.

The 2008 European Guideline of Testing for HIV Infection was the starting basis for the present guideline. In addition, the following guidelines and reports were reviewed in detail: UK National 2008 Guidelines for HIV Testing produced by the British Association for Sexual Health and HIV (BASHH), British HIV Association (BHIVA) and British Infection Society (BIS), Centers for Disease Control and Prevention (CDC) Revised recommendations for HIV testing of adults, adolescents, and pregnant women in healthcare settings, 2013 US Preventive Services Task force Recommendations for Screening for HIV Infection, The American College of Physicians Guidance Statement on Screening for HIV in Health Care Settings (2009), HIV Indicator Conditions: Guidance for Implementing HIV testing in Adults in Healthcare Settings, UNAIDS and World Health Organization (WHO) Working Group on Global HIV/AIDS/STI Surveillance Guidelines for Using HIV Testing Technologies in Surveillance: Selection, Evaluation, and Implementation, the WHO Guidance on provider-initiated HIV testing and counseling in health facilities, and the European Centre for Disease Prevention and Control HIV testing: increasing uptake and effectiveness in the European Union 2010.

Appendix 2

The system for describing levels of evidence and grading of recommendations is available at: http://www.iusti.org/regions/Europe/pdf/2013/Levels_of_Evidence.pdf

Appendix 3

Contributing organisations

A list of the organisations that contributed to the production of this guideline can be found at: http://www.iusti.org/regions/Europe/euroguidelines.htm

Appendix 4

A list of the members of the European STI Guidelines Editorial Board is available at: http://www.iusti.org/regions/Europe/pdf/2013/Editorial_Board.pdf