2008 European Guideline on HIV Testing

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Introduction

Testing for human immunodeficiency virus (HIV) is a procedure for the diagnosis or exclusion of HIV infection based on the detection of anti-HIV specific antibodies and/or specific viral proteins and/or viral RNA/DNA in an individual, usually from a blood sample.

The guideline represents an updated version of the 2001 European Guideline for Testing for HIV Infection, approved by the European Office of International Union against Sexually Transmitted Infections (IUSTI) and European office of the World Health Organisation (WHO), with the incorporation of several new developments.

The main purpose of this guideline is to provide advice on testing for HIV infection in individuals aged 16 years and older who have sought evaluation and treatment in sexually transmitted infection (STI) services or dermatovenerology clinics across Europe (referred to as STI clinics). Its aim is to provide practical guidance to clinicians in these settings who undertake HIV testing and suggest appropriate standards for the audit of service provision. The guideline may also be applicable in other clinical settings where HIV testing is required 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 the professional judgment of the clinician, consideration of individual patient circumstances and available resources.

Search Strategy

Evidence for this guideline was provided by review of the Medline/Pubmed, Embase, Google, Cochrane Library, and relevant guidelines up to February 2008. A Medline/Pubmed and Embase search was carried out from January 1981 to February 2008, looking for the following terms in the title or abstract: »HIV testing«, and »guideline(s)«, and »recommendation(s)<«; 19.783, 1.023 and 634 citations were identified, respectively. For some specific recommendations additional Medline/Pubmed search was performed when necessary. Google search was performed in November 2007 with the search term »HIV testing guideline(s)<« and all relevant documents of the first 150 search results were reviewed. A search of the Cochrane Library included Cochrane Database of Systematic Reviews, Database of Abstracts of Reviews of Effects and Cochrane Central Register of Controlled Trials. As mentioned earlier, 2001 European Guideline of Testing for HIV Infection were the main source for present guideline. In addition, the following guidelines and reports were reviewed in detail: 2006 UK National Guidelines on HIV Testing, 2006 UK National...
Screening and Testing Guideline on Sexually Transmitted Infections, a draft of the 2008 Guidelines for HIV Testing produced by British Association for Sexual Health and HIV (BASHH), British HIV Association (BHIVA) and British Infection Society (BIS) and all recent HIV testing guidelines produced by the US Centers for Disease Control (CDC) and WHO/UNAIDS.

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). These are indicated in bold type throughout the text e.g. (Ia, A).

Goals of HIV testing in STI clinics

The primary goals of HIV testing in STI clinics are:

- To provide pre- and post-test counselling for HIV-negative persons at risk of HIV transmission;
- To reduce the transmission of the HIV and other STI to others following a diagnosis of HIV;
- To identify HIV-infected persons as early as possible and immediately link them into appropriate medical management and care;
- To initiate partner notification with counselling, testing and referral to prevention services for partners of HIV-positive persons.

Benefits and harms of HIV testing

There are several important benefits from early self-knowledge of HIV infection, but there may also be some adverse effects. Knowing the diagnosis of HIV infection early, and thus being able to start highly active anti-retroviral treatment (HAART) before the onset of severe immunosuppression, has been shown to dramatically improve the life expectancy of the individual. HAART is also an important contributor in decreasing the risk of HIV transmission by reducing the viral burden and therefore infectivity of infected individuals. There is also consensus that it is the best to start HAART before the onset of severe immunosuppression indicating the need for testing asymptomatic, high risk individuals including those attending STI clinics. Current treatment guidelines may leave a period of up to several years between diagnosis of HIV infection and starting HAART. In this period however, behaviour change resulting from knowledge of HIV status may reduce high risk
behaviour, which will be influenced by partnership status, prevailing community norms, serostatus disclosure, psychosocial and medical care services available to the individual and other factors. A meta-analysis of 27 reports published from 1985-1997 suggested no significant impact of HIV testing and counselling on sexual risk behaviour. Recent studies, following the introduction of HAART show an ambiguous picture. On one hand, individuals diagnosed with HIV infection significantly reduce sexual and needle sharing risk behaviours, especially with uninfected partners, to whom they have disclosed their HIV status. On the other hand, individuals diagnosed with HIV may increase sexual risk behaviour, especially with casual HIV seroconcordant or assumed seroconcordant partners, because the main incentive for condom use – avoidance of HIV infection – does not apply anymore. Communication of HIV serostatus and disclosure in the setting of casual partnerships may frequently be non-explicit and selective. In addition, unprotected sex with HIV infected seroconcordant casual partners is associated with increased risks for other STI like syphilis and lymphogranuloma venereum.

When to consider HIV testing in STI clinics

- All individuals who seek evaluation and treatment in STI 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. (III, B)
- HIV testing and counselling should not be restricted to newly presenting patients but all previously HIV negative patients should be offered and encouraged to have HIV testing following possible re-exposure. (IV, C)
- Decisions on the frequency of re-testing should be adjusted according to the respective risk history, but should usually not exceed 3-4 times per year. In individuals with substantially more frequent risk exposures emphasis should be put on risk reduction counselling. (IV, C)

Due to limited resources, a particular STI clinic may not be able to comply with the recommendation to offer the test to all individuals who seek evaluation and treatment. In these circumstances, priority for HIV testing should be given to the following individuals who are at higher risk of HIV infection: (IV, C)

- individuals who strongly believe that they might have been exposed to HIV;
- individuals whose symptoms are compatible with acute retroviral illness or immunosuppression (comprehensive list of clinical features suggesting primary HIV infection available in Rogstat, 2006);
• individuals who practice unsafe sex, e.g. unprotected anal/vaginal sex or sex with multiple partners;
• individuals who have past/current history of STI particularly those associated with an increased risk of HIV transmission;
• individuals who have been the victims of sexual assault;
• individuals who are known sexual contacts of HIV infected patients;
• intravenous drug users with needle sharing behaviour that put them at risk;
• individuals who had sexual exposure in countries with a high HIV prevalence;
• individuals who have received blood transfusion or other blood products before introduction of routine HIV screening (in most European countries before 1985);
• any pregnant woman regardless of risk factors.

Pre-test assessment

The HIV pre-test assessment should be pragmatic and client centred. The main purpose of pre-test assessment is to obtain informed consent prior to the HIV test.

• Informed consent must be obtained before HIV testing and the tested person should give informed consent voluntarily.²
• Verbal communication is usually sufficient for the purpose of obtaining informed consent. (IV, C)
• 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.⁷ (IV, C)
• Detailed procedures how and when the patient will receive the result, with particular attention to the means by which a positive result will be delivered should be established and discussed during pre-test assessment. (IV,C) Try to avoid communicating results at times when ongoing support may be difficult, e.g. immediately before weekends and public holidays.¹

Recommended components of pre-test assessment

• Provide information on the clinical and prevention benefits of HIV testing including: health benefits of current treatments, the fact that knowing HIV status can allay
anxiety, that a positive test may motivate people to reduce risk activities and provide the opportunity to reduce the risk of transmission of the infection to others e.g. sexual partners, infants.

- Obtain a sexual history and history of other types of risk behaviour including date of last risk activity. Explore whether there are false beliefs about the mode of transmission for HIV or other STI.
- Assess the window period (the time period between exposure to infection and the HIV test becoming positive) and whether repeat testing is needed.
- Describe details of how and when the test result will be given.
- 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 programs, etc.
- Give an opportunity to ask questions.
- Obtain informed consent.

Provision of 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.\(^{23}\) (III, B) The information leaflet should be prepared in an easy to understand and informative way, and be available in the various languages commonly encountered in populations within the service area.\(^{6}\)

**Individuals who may require more in depth pre-test discussion**

In addition to information and topics mentioned above, a more in depth pre-test discussion should be available for those requiring or requesting it or to those at high risk of a positive result. Individuals who may require more in depth pre-test discussion include:\(^{2}\)

- those at high risk of HIV infection and their sexual partners (men who have sex with men; injecting drug users; people from countries with a high prevalence of HIV infection);
- patients with another STI or blood borne infection;
- patients with a psychiatric history/high level of anxiety/sexual or relationship issues;
- individuals who have been the victims of sexual assault/rape;
- individuals involved in commercial sex work;
- women who are or may become pregnant;
- adolescents below the legal age of majority.
Additional assessment for women who are, or may become, pregnant should include:

- the risks of transmitting HIV to the infant;
- measures that can be taken to reduce mother-to-child transmission, including antiretroviral prophylaxis and infant feeding counselling
- benefits to infants of early diagnosis of HIV infection.\(^7\) (**IV, C**)

For more details on HIV in pregnant women consult relevant national guidelines or, if not available, the CDC (www.cdc.gov/hiv) or BHIVA guidelines (www.bhiva.org).\(^5,6\)

Special considerations apply also in the case of adolescents in STI clinics 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.\(^7\) Since the legal framework, including the age of consent for sexual intercourse and offering treatment services to adolescents, varies between countries please consult relevant national guidelines. If a national guideline is not available advice is available from recent WHO/UNAIDS Guidance on provider-initiated testing and counselling in health facilities.\(^7\)

**Testing without informed consent**

HIV testing without informed consent is not recommended. 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.\(^2\)

**Confidentiality**

Individuals undergoing HIV testing should be informed that being tested, and their test result, will usually remain confidential.\(^1,2\) However, individuals should also be advised that confidentiality is not absolute and that health care provider 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 false name may be an option in some clinics for individuals who decline HIV testing due to concerns about confidentiality.\(^1\) (**IV, C**)

**Testing for HIV**

*Type of test*
• Venous blood is the preferred specimen for HIV testing. (IIa, B)
• HIV testing in samples other than venous blood should be avoided unless venepuncture is difficult or not possible.²,³ (IV, C)
• Should samples other than venous blood, such as finger prick blood, oral fluid or urine, be used in HIV testing, then a blood sample should be drawn for additional testing for all reactive or indeterminate tests. (III, B)
• Fourth generation screening assays which simultaneously test for anti-HIV-1 antibodies and HIV-1 p24 antigen as well as anti-HIV-2 antibodies are recommended to be used as HIV screening tests in European STI clinics.²⁴,²⁵ (IV, C) If available, fourth generation assays which also detect infection with HIV-1 group O should be used. According to the recent review of 10 fourth generation screening assays available in Europe, these assays have excellent sensitivities (99.78%–100%) and specificities (99.5%–99.93%).²⁵,²⁶
• Nucleic acid amplification tests (HIV-1 viral load assays) are not recommended as a diagnostic screening assay because of an only marginal advantage over fourth generation screening assays for detecting primary HIV infection and the possibility of false positive results.²⁷-²⁹ (IV, C)
• In point-of-care (POC) settings the health-care provider using rapid HIV tests should be aware that currently these do not test for HIV-1 p24 antigen and may be false-negative during primary HIV infection³⁰-³² or during advanced AIDS.³³ (III, B)
• Point-of-care tests that use sample types other than blood, such as oral fluid or urine, may be subject to more sampling variation which influences the sensitivity of the test and limits their suitability as a screening testing in a STI clinic setting.³³ (IV, C) They are recommended only in certain settings, such as needle-phobic patients and for screening high risk children where referral to a paediatric phlebotomist is impractical.³¹ (IV, C)
• Sites using point-of-care tests should be overseen by the local laboratory and have a robust quality assurance programme.³⁰,³² (IV, C)
• Self-testing for HIV³⁴ - a procedure in which all stages of the HIV test take place in the patient’s home is not recommended at present. (IV, C)

Confirmation of positive results
• Any reactive or indeterminate screening test result should be confirmed with a more specific test which preferably tests with different method/antigens.³⁵ (III, B)
• Confirmation of reactive screening test results should be performed in a laboratory with experience in HIV confirmation. (IV, C)
• Line-Immuno Assay (LIA) and/or Western blot (WB) which distinguish between the different antibodies against the individual HIV-1 and HIV-2 antigenic components is the preferred final confirmation assay. (IV, C)

• The final laboratory report must clearly indicate whether the patient has an HIV-1 or HIV-2 or dual confirmed infection. (IV, C)

• An additional separate second blood sample should be tested for confirmation of HIV infection to exclude mislabelling, contamination or misidentification. (IV, C)

• Nucleic acid amplification tests for HIV i.e. HIV-1 viral load or proviral DNA testing as well as HIV-1 p24 antigen testing with a neutralisation step can be employed to diagnose seroconversion where the initial screening test gives a weak positive or negative results, but where seroconversion is strongly suspected. (IIb)

• Viral load assays are not licensed for diagnostic testing and both false-positive and false-negative HIV-1 viral load results occasionally occur\(^{27-29}\) when used in a confirmatory setting. In particular, low values of HIV-1 RNA (less than 5,000 copies/ml) should be interpreted with caution and probably not viewed as positive unless it is confirmed on a subsequent test. (IIb)

Quality control

• All HIV testing and confirmation should be subject to strict quality control. All laboratories should belong to an accreditation scheme that monitors quality assurance. (IV, C)

• Only Conformité Européenne (CE) marked tests should be used for HIV testing. (IV, C)

• Point-of-care testing should be subject to the same strict quality assurance principals as practiced by accredited laboratories. (IV, C) This includes using standard operating procedures (SOP), regular use of external controls and an external quality assessment process. Regular on-site audits should be performed to observe if standard operating procedures are adhered to, records are maintained, adequate training is provided, internal and external quality standards are used and selected samples are validated in a reference laboratory.\(^{30,31,36}\)

• Plasma/serum samples should be stored post testing according to local regulations and longer if possible. (IV, C)

• Laboratories should provide their latest external quality control scores to their users upon request. (IV, C)

Interpreting HIV test results

Health-care providers who order HIV tests should be familiar with basic laboratory terminology such as sensitivity, specificity, negative and positive predictive value of tests.
This is not only helpful to interpret the test result correctly, but also to give an unambiguous answer to the patient during post-test discussion. The health-care provider should be especially aware of:

- what HIV testing algorithm their laboratory is using;
- what HIV screening test (third or fourth generation) their laboratory is using;
- capability of 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 regarded as non-infected unless the patient presents with symptoms of primary HIV infection or has a history of recent high risk exposure. (IV, C)
- It is recommended that patients have a baseline HIV test done at presentation and, if necessary, repeated at 3 months from the time of high risk exposure. (IIb, B)
- Individuals with a high risk exposure to HIV should not be fully reassured until at least 3 months have passed during which they remain seronegative.37 (IV C)
- Recalling individuals for a follow-up longer than 3 months should be considered only exceptionally e.g. if post exposure prophylaxis was given for occupational exposures, where the tested subject has an substantially impaired ability to develop antibodies and where there is microbiologically proven simultaneous infection with another viral pathogen such as human cytomegalovirus or hepatitis C virus.3,38,39 (IV, C)
- 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 specialised laboratory for analysis using alternative screening tests or molecular tests to exclude uncommon HIV strains is recommended. (IV, C)

**Interpreting positive HIV test results**

- A person should not be told that he/she is HIV positive based on an initial result of screening tests alone. (IV, C) Two further confirmatory tests will establish with a high degree of certainty whether the person is truly infected with HIV.
- Testing of a follow-up specimen is a critical safeguard against human error. In all individuals with an initial confirmed positive HIV test result, a second blood sample should be obtained to exclude mislabelling, contamination or misidentification. (IV, C)
- Attention should be paid whether HIV-1 or HIV-2 (or both) has been diagnosed since 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 with either the first or second confirmatory test, a result of “indeterminate” should be given and a second blood sample should be requested. (IV, C) The first and second blood sample should be separated by at least 2 weeks. A plasma sample is the preferred second specimen. (IV, C)
- Weakly-reactive results which cannot be confirmed or do not become reactive on a subsequent sample are indicative of a non-specific reaction i.e. false positive result. (IV, C)
- If the fourth generation screening test is positive but the third generation screening test and/or confirmatory line immunoassay/western blot test is negative, then a high possibility of seroconversion exists. The best strategy in this situation is to obtain a follow-up specimen. (IV, C) If on the follow-up sample the fourth generation test and the third generation screening test are both clearly positive, then a diagnosis of seroconversion can be made without further testing. Alternatively, the initial specimen can be tested using a separate HIV-1 p24 antigen test with neutralization or a nucleic acid amplification tests to diagnose early seroconversion. All results should still be confirmed on a follow-up specimen. (IV, C)

Post test issues

Fortunately, the majority of HIV tests performed in STI clinics are negative. However, when the individual receives their result it provides an opportunity to encourage future safe sex behaviour.1

- 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)
- Post-test discussion for individuals with positive or inconclusive test results should be done face-to-face whenever possible. (IV, C)
- The HIV test result and its delivery should remain confidential. (IV, C)

Post-test discussion for individuals who are negative
• Discuss the window period and address the need for a repeated test in those with high-risk behaviour within the last 3 months.
• Encourage safe sex behaviour, particularly addressing behaviour change regarding unsafe sex or the maintenance of safer sexual practices.
• 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 programs, etc.
• Options for HIV prevention should be discussed if appropriate and condoms provided.
• Post exposure prophylaxis (a short course of anti-retroviral drugs given shortly after potential exposure to HIV) may be appropriate in certain situations depending on local guidelines.

Post-test discussion for individuals with inconclusive test results

• An explanation should be provided on the significance and possible reasons for an inconclusive HIV test result.
• The nature of the additional tests which 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 nucleic acid amplification testing or HIV-1 p24 antigen testing, particularly for pregnant women who have not been tested previously.

Post-test discussion for individuals who are positive

The HIV positive result should be given in a confidential environment and in a clear and direct manner. Patients are often very distressed when first informed about a positive HIV test result. They are faced with major adaptive challenges, such as accepting the possibility of a shortened lifespan, coping with other people’s reactions to a stigmatizing illness, and with developing and adopting strategies for maintaining physical and emotional health. 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:
• Inform the patient straightforwardly that the HIV test was positive.
• Obtain a second blood sample and arrange for a repeat test to confirm the result.
• Make sure that the patient has understood the implications of a positive test.
• 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.
• Schedule a new consultation in the near future, e.g. next day.
• Screening tests for gonorrhoea, chlamydia and syphilis should be offered

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
• Inform the patient about the HIV result from second sample and confirm that the HIV diagnosis is definite.
• Inform them about 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 HAART.⁴²
• Assess the need for psychological support or contact with other services, e.g. drug dependency, and refer as necessary.
• Address how to avoid transmitting HIV and other STI (if applicable) to others.
• Discuss safe sex, use of condoms, not sharing needles, etc.
• Discuss the need for partner notification.

Regarding the seropositive woman, there are some particular issues which should be included in the counselling at an early stage:¹
• Discuss the implications for possible future pregnancy: the risks for the child and the need for antiretroviral therapy during pregnancy. Inform that antiretroviral treatment if administered to women during pregnancy and to the child for a short period of time can significantly reduce this risk of mother-to-child transmission.⁴³,⁴⁴
• If already pregnant, discuss the implications. Further guidance should be sought from relevant national guidelines or, if not available, from the Centers for Disease Control (www.cdc.gov/hiv) or the British HIV Association (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 STI and repeated sexual risk reduction counselling in a context of sympathetic, non-judgemental sexual history taking.ª

Non attendance for positive results

- An agreed recall process following failure of a patient to return for a HIV positive result should be established. (IV, C)
- Attempts should be made to contact the patient where possible. (IV, C)
- Contact options should be discussed with the patient at the testing visit where possible. (IV, C) Efforts may include making telephone calls, sending letters or making home visits.

Voluntary disclosure, partner notification and contact tracing

Partner notification or partner referral is a cornerstone of STI programmes worldwide.45 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 sexual partner(s) and to any new sexual or needle sharing partner in addition to using condoms during sexual intercourse.¹ (IV, C)
- Notification of previous sexual and needle sharing partners is also advised. This is usually done on a case by case basis working back from the present partner to the time when they had a negative test.¹
- Sexual partners and those who share needles with HIV-positive persons, and who are or have been at risk for being infected with the virus, should be counselled and tested for HIV.41 (IV, C)
- Testing of the children of HIV positive women is recommended unless the woman was known to be HIV negative during her previous pregnancies. (IV, C)

Appropriate approaches to inform the partners of index patients are:¹

- **Patient referral.** The health care provider and the patient agree that the patient will notify his or her own partners.
- **Provider referral.** The health care provider and the patient agree that the health care provider informs the partner(s). The issue of under what circumstances, if any, the
name of the index patient will be disclosed needs to be clearly discussed, and needs to take into account the professional, ethical and legal situation in the individual country. The amount of information which will be provided to those who have been exposed to HIV should be agreed with patient.

Partner notification is a challenge for any healthcare system. Attitudes towards people at risk of being HIV infected, social values, the ability to communicate and to what degree the patient has trust in the system are factors that are crucial to the success of any partner notification programme.¹
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Appendix 1

Levels of evidence and grading of recommendations

Levels of Evidence

Ia  Evidence obtained from meta-analysis of randomised controlled trials.
Ib  Evidence obtained from at least one randomised controlled trial.
IIa Evidence obtained from at least one well designed study without randomisation.
IIb Evidence obtained from at least one other type of well designed quasi-experimental study.
III Evidence obtained from well designed non-experimental descriptive studies such as comparative studies, correlation studies, and case control studies.
IV  Evidence obtained from expert committee reports or opinions and/or clinical experience of respected authorities.

Grading of Recommendations

A (Evidence levels Ia, Ib)
Requires at least one randomised control trial as part of the body of literature of overall good quality and consistency addressing the specific recommendation.

B (Evidence levels IIa, IIb, III)
Requires availability of well conducted clinical studies but no randomised clinical trials on the topic of recommendation.

C (Evidence IV)
Requires evidence from expert committee reports or opinions and/or clinical experience of respected authorities. Indicates absence of directly applicable studies of good quality.
Appendix 2

Declarations of Interest

Declarations of interest:
Mario Poljak – none
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