TECHNICAL REPORT

HIV testing: Increasing uptake and effectiveness in the European Union

Evidence synthesis for Guidance on HIV testing

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Contents

Abbreviations

AIDS	Acquired immunodeficiency syndrome
CDC	United States Centers for Disease Control and Prevention
EEA/EFTA	European Economic Area/European Free Trade Association
ECDC	European Centre for Disease Prevention and Control
EU	European Union
GP	General practitioner
HAART	Highly active anti-retroviral therapy
HIV	Human immunodeficiency virus
IDU	Injecting drug user
MSM	Men who have sex with men
STI	Sexually transmitted infection (or sexually transmitted disease)
UNAIDS	Joint United Nations Programme on HIV/AIDS
WHO	World Health Organization

Definitions

HIV screening: Performing an HIV test for all persons in a defined population.

Targeted HIV testing: Performing an HIV test for subpopulations of persons at higher risk, typically defined on the basis of behaviour, clinical or demographic characteristics.

Opt-in testing: HIV testing is offered but the individual is required to actively give permission before it is performed.

Opt-out testing: Performing HIV test after notifying the individual that 1) the test will be performed, and 2) the individual may elect to decline or defer testing. Consent is inferred unless the individual declines testing.

Informed consent: A process of communication between individual and test provider through which an informed individual can choose whether to undergo HIV testing or decline to do so. Elements of informed consent typically include providing oral or written information regarding HIV, the risks and benefits of testing, the implications of HIV test results, how test results will be communicated, and the opportunity to ask questions.

Pre-test counselling: An interactive process prior to an HIV test where an individual risk assessment is undertaken and specific behaviours that increase the risk for acquiring or transmitting HIV are identified, and tailored prevention information is delivered.

Executive summary

HIV testing efforts in European countries are failing to identify HIV infections early, with high proportions of undiagnosed and late-diagnosed infections. This review presents a synthesis of available literature on the benefits of testing for HIV, barriers to testing and effective strategies to overcome these barriers and increase HIV testing and diagnoses, while ensuring access to treatment and care.

There is strong evidence that an early diagnosis of an HIV infection and subsequent treatment can result in a markedly improved prognosis for the individual who can expect low morbidity, a good quality of life, and a near normal life expectancy. There is also evidence of the public health benefit of HIV testing through the adoption of safer sexual behaviour by diagnosed individuals and a reduced infectiousness related to antiretroviral treatment. The cost of treatment and care for individuals diagnosed early is significantly lower than for those diagnosed at a late stage of infection. In the United States and France, routine one-time testing has been found to be cost effective, even in low HIV prevalence populations. Cost effectiveness is improved when secondary transmission benefits are included and when newly diagnosed patients are successfully linked to HIV treatment and care.

Barriers to HIV testing are well described in Europe, with the majority of studies focusing on the needs of sub-Saharan African and Men who have Sex with Men (MSM) populations. Barriers exist at the individual, healthcare provider, and institutional level, with some overarching issues such as low risk perception, fear and stigma around HIV, and lack of knowledge about HIV testing policies and information around the test itself.

This review identified evidence for a number of strategies to overcome these barriers. Mass media campaigns can have an impact on testing behaviour, with most HIV testing campaigns successfully increasing HIV testing rates in the short term. Reducing stigma around HIV testing and diagnosis can be addressed at the institutional level through 'normalisation' of the testing procedure and the introduction of a universal offer of testing. This approach has found high levels of uptake and acceptability among patients in a variety of settings including antenatal and STI services. Training healthcare providers can effectively increase HIV testing rates and improve healthcare providers' attitudes towards HIV and confidence in conducting a test.

Written informed consent has been identified as a barrier to testing, and verbal informed consent is acceptable alternative and results in higher testing uptake. Similarly, studies have shown that providing brief pre-test information rather than pre-test counselling is acceptable to the patient and results in an increased offer and uptake of an HIV test in a wide range of settings. Although newly diagnosed individuals greatly benefit from post-test counselling, brief post-test information may be given to those testing negative in place of counselling. Innovative ways of providing pre- and post-test information have been trialled, including use of printed information and video technology, and have largely been found acceptable to patients, particularly in busy or poorly resourced settings. However, there exists a trade-off between increasing HIV testing rates and delivering tailored risk assessments and prevention information through streamlining the pre- and post-test counselling process. The use of rapid (or point-of-care) testing technologies has been trialled with similar success and the additional benefit of increasing receipt of results compared to conventional HIV tests.

The review identified some important gaps in our knowledge. Few high quality studies were conducted in the area of HIV testing in Europe, particularly regarding testing in non-traditional settings, such as acute and primary care settings and prisons, and the cost-effectiveness of HIV testing. Much of the evidence in the review has been therefore drawn from studies conducted in the United States. Although many findings can be extrapolated to the European context, both the healthcare system and the HIV epidemic in the United States have many unique features.

Nonetheless, there exist many evidence-based strategies and approaches to expand HIV testing that may reduce the numbers of undiagnosed and late-diagnosed HIV-infected individuals. These findings highlight the need to expand testing across Europe and the necessity to ensure that HIV programmes are vigorously monitored and evaluated at the local and national level.

1 Introduction

1.1 Background

HIV infection is one of infectious diseases associated with the highest morbidity and mortality in the countries of the European Union and European Free Trade Association (EU/EFTA) (Appendix 1). Despite the development of effective therapies which improve life expectancy for people diagnosed with HIV, a significant proportion of HIV-infected Europeans remain undiagnosed and are diagnosed at a late stage of infection. Individuals who are unaware of their infection may unknowingly transmit HIV to others, and are at increased risk of HIV-related morbidity and mortality, resulting in high costs to the healthcare system. The promotion of HIV testing and thus earlier diagnosis therefore will have a major impact for the individual, in terms of improved prognosis, and for the population due to possible reduction in the onward transmission of HIV.

The European Centre for Disease Prevention and Control (ECDC) intends to develop a technical guidance document on HIV testing in close collaboration with key stakeholders. ECDC supported an earlier study, undertaken by the University of Ghent, which reviewed HIV testing policies, practices and barriers to testing. Results of the study showed that while most EU countries have national policies on antenatal HIV testing, policies in other settings and populations vary widely between countries. Furthermore, EU countries' testing practices revealed high heterogeneity and testing strategies often lack an evidence base.

The onus is now on European countries to adopt a strategic, evidence-based approach to develop and implement effective HIV testing interventions and to ensure equal access for all European citizens to HIV testing and counselling services. The objective of this review is to present a synthesis of the evidence from Europe and the developed world on strategies to improve the effectiveness of HIV testing to inform the development of a guidance document for HIV testing in Europe.

1.2 Epidemiology of HIV in Europe

There are an estimated 850,000 people living with HIV in Western and Central Europe [1] and approximately 30% of individuals living with HIV in the EU have been estimated to be undiagnosed [2]. In 2008, more than 25,600 newly diagnosed cases of HIV were reported in the countries of the EU and European Economic Area (EU/EEA), representing a rate of 6.1 per 100,000 population [3]. The epidemic of HIV infection in Europe continues to disproportionately affect three sub-populations:

- men who have sex with men (MSM);
- migrants from high-HIV-prevalence countries; and
- injecting drug users (IDU).

The majority of infections were probably acquired through sexual contact in Europe, with sex between men accounting for 40% of infections and heterosexual contact accounting for 29% new diagnoses in 2008, when HIV diagnoses in individuals from countries with generalised epidemics are excluded. A large proportion (42%) of individuals infected heterosexually originated from countries with generalised HIV epidemic so this group also represents a high-risk group. Around 6% of infections were reported to be transmitted through injecting drug use, although this proportion is considerably higher in the southern and eastern parts of the European Union. Rates of AIDS and deaths have been in steady decline since the advent of effective treatment.

Late diagnosis (defined as an HIV diagnosis at a stage after which treatment should be started) is not measured at the European level, but a 2007 survey of EU/EFTA countries found between 15 and 38% of all HIV infections across Europe were diagnosed late [4]. With recent treatment guidelines recommending initiation of antiretrovirals at higher CD4 thresholds, this proportion is expected to increase [5].

1.3 Aims

As set out by the tender by ECDC, the aims of the evidence synthesis are as follows:

1. Provide an update of existing reviews and meta-analysis on individual and public health effects of HIV testing, taking into account publications on positive effects and benefits (e.g. earlier access to treatment, reduced transmission), the societal context of HIV testing (e.g. stigma), cost-effectiveness, and adverse effects.

2. Provide a synthesis of the evidence for interventions, activities, programmes, and policies aimed at:

- raising awareness of risk at the individual, community, societal and structural level;
- raising motivation of persons to be tested and of health professionals to offer HIV testing. The specific situations for risk groups and most vulnerable groups have to be taken into account;

- guarantee of high quality of the testing process itself (pre-test counselling, consent, opt-in/opt-out approaches, rapid tests, home testing, risk assessment, clinical indication, frequency of testing, guidelines and quality assurance); and
- follow up after HIV testing (post test counselling, referral to clinical and psychosocial care and support).

2 Methods

2.1 Computerised literature search

A computerised literature search of Medline was undertaken using the NHS Evidence Health Information Resources website (formerly the National Library for Health) (www.library.nhs.uk). Key terms were used to search article titles and abstracts and MESH terms. The search strategy can be found in Appendix 1.

The computerised search was limited to the most recent evidence (papers published 2005 and later) and to human studies. This resulted in the review of 2829 publications relating to HIV testing in EU and EEA/EFTA countries and the United States, Canada, and Australia published between January 2005 and April 2010. To ensure that we achieved a high sensitivity in identifying the appropriate bibliography, we undertook a number of quality control checks using PubMed.

One reviewer screened document titles using the following exclusion criteria:

- publications describing non-HIV testing;
- publications where no HIV-testing-related intervention was described, including surveillance papers (except where surveillance data was used to assess the impact of a national HIV testing programme or policy change), commentary and opinion pieces, laboratory-based studies, drug monitoring and resistance studies, and vaccine studies;
- studies undertaken among children or in occupational health settings;
- studies conducted outside EU and EEA/EFTA countries, United States, Canada and Australia; and
- publications in languages other than English where no translation could be found.

Abstracts were then appraised independently by two reviewers, who compared results and discussed discrepant decisions until an agreement was reached. Full papers were then obtained and reviewed for inclusion for data extraction and review.

The results of the literature search were as follows:

- 2829 documents for title screening
- 591 documents for abstract screening
- 171 documents agreed for full paper screening
- 118 papers included for data extraction and review

2.2 Manual bibliography search

Manual searches of the bibliography of publications identified through the computerised literature search were completed. The primary objective of this search was to identify key papers published prior to 2005; however no limitations were placed on date of publication. Results of this search were limited to human studies conducted in EU and EEA/EFTA countries, the United States, Canada, and Australia.

This review yielded 146 papers for data extraction and review.

2.3 Grey literature

A manual internet key word search using Google Scholar was conducted to identify grey literature including country-specific and international HIV testing programme documents and guidelines. In addition, Julia del Amo from the Migrant Health Project supplied testing policy documents from all EU/EFTA countries.

Conference abstracts were also reviewed from the following conferences, using the search terms 'HIV' and 'test':

- 2005–2010 British HIV Association Annual Conference
- 2009 European AIDS Clinical Society annual European AIDS conference
- 2010 Conference on Retroviruses and Opportunistic Infections
- 2008 XVII International AIDS Conference
- 2010 XVIII International AIDS Conference

A total of 26 programme documents and guidelines and 18 conference abstracts were identified and included for review.

2.4 Grading of evidence

Evidence presented in sections 3.2 Barriers to testing, 3.3 Strategies to increase HIV testing, and 3.4 Testing approaches by setting was graded according to criteria developed by the US Department of Health and Human Services' Agency for Healthcare Policy and Research for grading scientific evidence, now known as the Agency for Healthcare Research and Quality [6]. See Appendix 3 for grading criteria. Total number of studies and grading has been listed at the beginning of each sub-section.

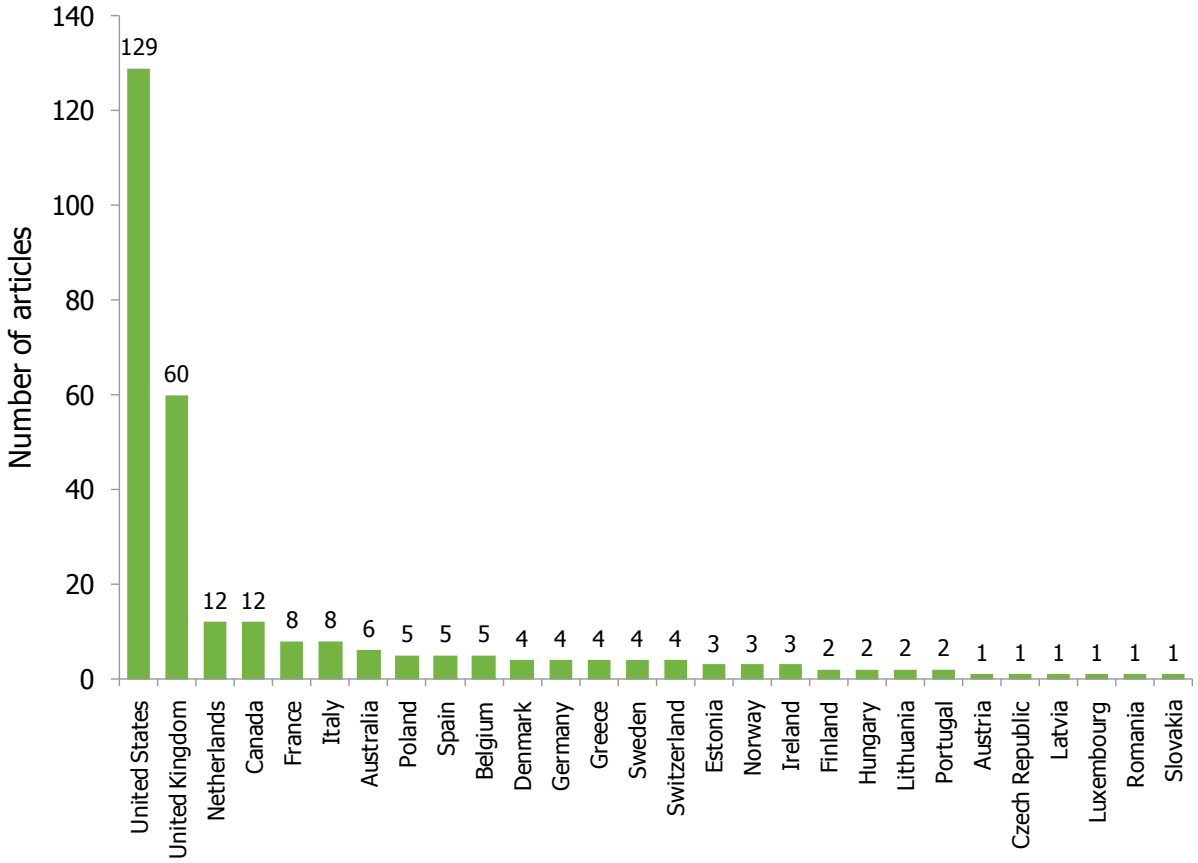
3 Results

The evidence gathered through the literature search is summarised under the following headings, which were identified as central to increasing effectiveness of HIV testing:

- individual and public health effects of HIV testing and treatment;
- barriers to testing at the individual, health care provider and institutional levels;
- strategies to overcome barriers and increase effectiveness of HIV testing:
  - raise awareness of HIV and motivation to test;
  - aspects of the testing procedure;
  - optimal frequency of testing;
  - ensuring access to care and follow up after HIV diagnosis;
- testing approaches by setting.

Table 1 shows the distribution of studies included in the evidence synthesis by country of origin. The majority of studies were from the United States, followed by the United Kingdom, with modest representation from other western European countries, Australia, and Canada. This review is limited by the lack of evidence from Europe and uncertainty over the generalisability of research conducted in the United States to the European context, particularly the eastern part of Europe.

Figure. Distribution of studies by country



Note: Studies conducted in multiple countries were assigned to each country so will be counted more than once. EU/EFTA countries where no studies were identified were Bulgaria, Cyprus, Iceland, Liechtenstein, Malta, and Slovenia.

3.1 Individual and public health effects of HIV testing and treatment

Historically, the prompt diagnosis of HIV infection was of minimal benefit to the individual who had a poor prognosis in the absence of effective treatment. Since the mid-1990s, the benefits of diagnosis and treatment on combination antiretroviral therapies have been extensively documented with year-on-year improvements on the health of HIV-infected individuals. More recently, evidence of the public health benefit of testing and treatment has

emerged. This section summarises the benefits and any adverse effects associated with HIV testing and subsequent treatment.

Reduced mortality and morbidity

The advent of effective antiretroviral therapy has improved the prognosis for individuals with HIV infection. A recent WHO/UNAIDS report estimates 2.9 million lives have been saved as a result of access to antiretroviral therapy (HAART, highly active anti-retroviral therapy) [1]. In countries where antiretroviral therapy is widely available, access to treatment has greatly reduced HIV-related mortality and morbidity [7–14]. The EuroSIDA study analysed data from patients in 70 European HIV centres and found a fall in HIV-related deaths from 14.6 per 100 person-years pre-HAART to 1.5 post-HAART [15]. Over the same period, numbers of people diagnosed with AIDS-defining illnesses fell from 27.4 per 100 pre-HAART to 2.6 per 100 late-HAART [15]. The CASCADE cohort study, conducted in Europe, Canada and Australia, found excess mortality among HIV-infected persons in comparison with HIV-uninfected persons declined by 85% following the introduction of antiretroviral therapy, suggesting mortality rates among people living with HIV now approach those in the HIV-uninfected population [16]. This trend is reflected in national and international HIV surveillance data which have shown a strong temporal relationship between access to treatment and AIDS diagnoses and a decrease in AIDS- and HIV-related deaths [3,17-22].

Improved life expectancy

Reduction in AIDS-related deaths across Europe has resulted in improved life expectancy of persons infected with HIV. Predicted life expectancy with effective antiretroviral therapy varies; however mathematical modelling studies estimate between 20 and 50 years of life remain for individuals who start therapy at 20 years of age [23–26]. A Danish population-based cohort study estimated a median survival of more than 35 years for a young person diagnosed with HIV infection after 2000 [27]. Factors associated with shorter life expectancy include injecting drug use, antiretroviral regimens with less than three drugs, and importantly, immunosuppression. Up to 50% reduction in life expectancy is estimated in patients with CD4 < 200 cells/m^3 at the time of starting therapy [23–25]. Early diagnosis is therefore a key strategy to prevent progression of HIV to advanced stage of disease.

Effect of antiretroviral therapy on transmission

There is growing evidence that widespread access to treatment may reduce HIV incidence by reducing viral load at the population level [28]. A recent meta-analysis from researchers at WHO estimates the transmission rate from an individual on treatment is approximately 0.5 per 100 person-years, compared to 5.6 per 100 person-years for an individual not on treatment [29]. Several mathematical models have estimated a substantial decrease (37–63%) in HIV incidence with treatment, although these models are limited by assumptions about stable risk behaviour [30–32]. These data have led some to advocate for greater antiretroviral use in the prevention of HIV [33). Further research in this area is needed to assess the use of antiretroviral therapy as a strategy for HIV prevention, however retrospective evidence of an association between antiretroviral therapy and population-level decreases in new HIV diagnoses is emerging from the United States and Canada [34,35]. The results of a multi-centre randomised controlled trial to determine the effectiveness of antiretroviral therapy in preventing the sexual transmission of HIV in HIV-serodiscordant couples are expected in 2012 [36].

Behaviour change following HIV testing

Knowledge of one's HIV status has been associated with a reduction in risk behaviour in HIV-positive individuals, with less evidence of benefits in HIV-negative individuals. Three systematic reviews found that testing with pre- and post-test counselling was effective in reducing sexual risk behaviour among HIV-positive individuals, with no significant change in risk behaviours in HIV-negative individuals after testing [37–39]. There is good evidence from the UK and the United States that HIV testing and counselling is an effective strategy to reduce the risk of onward transmission among people with diagnosed HIV, through increased condom use with partners of unknown or negative HIV status and having fewer sexual partners [39–41]. This suggests that post-test counselling following a positive result may be more influential on behaviour change, compared to pre-test counselling or post-test counselling of negative individuals. This is supported by evidence from randomised controlled trials from the United States which show that replacing standard testing and counselling with alternative testing methods (rapid testing, nurse-initiated testing, and brief counselling) resulted in a similar impact on sexual risk behaviour following testing [42,43].

A meta-analysis of eight studies from the United States comparing the rates of self-reported unprotected intercourse of HIV-positive persons both aware and unaware of their status, found that rates of unprotected intercourse were 53% lower in individuals who were aware of their HIV status compared to those unaware [44]. When adjusted for partner's HIV status, rates of unprotected sex were reduced by 68% with partners of negative or unknown HIV status. One meta-analysis estimates an HIV transmission risk 3.5 times lower in the HIV-positive patients aware of their status compared to those unaware, attributed to positive behavioural change following diagnosis and risk reduction associated with low viral load [45].

However, a substantial proportion (13–19%) of HIV-infected individuals continue to report behaviour that increases the risk for transmission, such as inconsistent condom use and multiple partners [40,46–48]. These findings are consistent with behaviour surveillance data among MSM in Europe [49–51].

Regarding changes in risk behaviour among IDUs, the data is less conclusive. A cross-sectional study from Estonia found that 36% of HIV-positive IDUs who were aware of their serostatus had shared injecting equipment in the past month, compared to 22% of IDUs who were HIV positive and unaware of their serostatus and 25% of HIV-negative IDUs [52]. Two studies from the United States (one randomised trial and one prospective study) found that after testing, there was no difference in drug use or reported injection equipment sharing between HIV-positive and HIV-negative IDUs [53,54]. In contrast, a European multi-country cross-sectional study of IDUs found that HIV-positive IDUs who were aware of their status reported less risky behaviours than those untested or not infected [55,56] The three studies that measured sexual risk behaviour found no differences in unprotected condom use after HIV testing, regardless of HIV serostatus [52–54). Two randomised trials from the United States found that extensive counselling and education programmes were effective at reducing drug use behaviours and risky sexual behaviour among IDUs compared to standard counselling [57,58].

Cost-effectiveness

The projected lifetime cost of treatment and care of HIV-infected individuals is substantial, with the cost of treatment and care for late-diagnosed individuals considerably higher. Costs of late diagnosis are high, with a Canadian study reporting that HIV-infected patients with CD4 less than 75 cells/mm3 cost over 2.5 times more per month to treat compared to patients with CD4 greater than 200 cells/mm3, with inpatient hospitalisation costs accounting for most of the difference [59].

Cost-effectiveness of HIV testing depends on HIV prevalence, testing and counselling costs, and whether newly diagnosed individuals enter into care. In France, an evaluation of HIV testing strategies was undertaken under the auspices of the Haute Autorité de Santé which was based on a systematic literature review and a cost-effectiveness analysis. In the cost-effectiveness analysis, the systematic offer of an HIV test in the general population, populations at high risk (e.g. MSM, IDUs) as well as areas of high prevalence (the French overseas departments in South America) was compared to the current situation of client-initiated testing [60]. A WHO-defined threshold of three times the GDP (equal to EUR 81,900) was used to assess cost-effectiveness. In the resulting analyses, cost-effectiveness was demonstrated by a one-off HIV test in the general population and regular HIV testing in populations at high risk and in areas of high prevalence.

Two modelling studies from the United States found one-time HIV testing in high-risk hospital outpatients (HIV prevalence 1%) to be cost effective (USD 38,000 to USD 42,000 per QALY gained) compared to no testing [61;62]. When benefits of reducing onward transmission were directly incorporated into cost-effectiveness ratio estimates, the cost-effectiveness improved to USD 15,000 per QALY [61]. One-time testing remained cost-effective in populations with low HIV prevalence (between 0.05% and 0.1%) [61–63]. The studies found three- or five-yearly testing of high-risk populations (at least 1.0% prevalence and 0.12% incidence) to be cost-effective only when transmission benefits were included, and annual testing was not cost-effective in any population [61;62]. One-time screening in the general population approached the threshold for cost-effectiveness and warrants further investigation [62].

Testing strategies have a strong impact on cost-effectiveness. One United States study found that ensuring receipt of test results and entry into care after a positive diagnosis had a greater impact on cost-effectiveness than increasing testing rates [64]. A recent analysis of cost-effectiveness of HIV counselling and testing strategies showed that nurse-initiated routine screening with rapid HIV testing and brief counselling was cost-effective compared with standard HIV testing and counselling strategies, through increased rates of testing and receipt of test results [65].

3.2 Barriers to testing

Awareness of the barriers to HIV testing from the perspective of the individual, the test provider, and at the institutional level is an essential part of designing effective HIV testing programmes. Numerous quantitative and qualitative studies have been conducted in Europe to identify the barriers to HIV testing in the general population as well as specific sub-populations, resulting in four systematic literature reviews [66–69].

Barriers at the individual level

Evidence included: 17 Grade III studies

Low perception of individual risk is an important barrier to testing. Thirteen Grade III European studies have found that perception of risk is highly influential in an individual's decision to accept an HIV test, concluding that people who do not perceive themselves to be at risk of infection are less likely to test [66,67,69,70]. In a survey of newly diagnosed HIV-positive Africans living in the UK, nearly 70% of respondents reported that they had not considered the possibility of being HIV positive prior to diagnosis, the majority of whom were not expecting a positive result at the time they tested HIV positive [71]. In a large survey of Dutch MSM, respondents stating that they had never

taken an HIV test, frequently cited low-risk perception as a reason for not taking an HIV test although over half of them reported risky sexual behaviour [72]. A review of studies on sub-Saharan African migrants in Europe revealed that despite high levels of HIV knowledge within African communities, this did not translate into perceived individual risk [69,73,74]. Another study of sub-Saharan Africans in Belgium found that while survey participants were able to accurately identify risky sexual behaviour, these behaviours were categorised as immoral and participants did not perceive themselves as personally engaging in such behaviours; subsequently they did not feel the need to take an HIV test [75]. Those at highest risk may be most susceptible to inaccurate self-assessment of risk. Two studies on MSM from Scotland and the Netherlands found that those at higher risk (with multiple partners, high rates of unprotected anal intercourse, and an STI diagnosis) had low self-perception of risk and incorrect assumptions about the HIV status of their partners, and as a result tested less frequently than other MSM [76,77]. Likewise, two studies of sexually transmitted infection (STI) clinic attendees in the Netherlands and the UK found that those who had engaged in higher risk behaviours appeared less likely to opt for an HIV test [78,79].

Fear was reported to be a significant barrier to testing in five Grade III European studies. Fear of the negative social consequences of a positive diagnosis (stigma, discrimination, rejection) was highlighted as more important than fear of death or illness among all populations, including migrants and MSM [67]. This fear remained even among individuals who were able to accurately assess their personal risk [75]. The perception of HIV infection as a deadly disease rather than a manageable condition was more common among migrant populations than among non-migrants [66]. This research also highlighted that people are more motivated to test when they perceive a benefit to diagnosis, but exactly which benefits promote HIV testing are not clear, although it appears that the medical benefits alone are not sufficient to encourage more testing uptake [67]. Fear of stigma and negative response from healthcare providers were also a barrier to HIV testing for migrant populations [75,80]. A systematic review found that the fear of HIV-related stigma is strongest amongst those dealing with other pre-existing stigmas, such as that associated with being a migrant, an IDU, or homosexual [68]. Individuals with HIV indicator diseases may experience additional barriers due to stress related to the initial diagnosis or fear of added stigma. A qualitative study of tuberculosis patients in the UK found that most respondents who were offered HIV testing initially declined because they were worried about the outcome and the possibility of stigmatisation [80]. A systematic review specifically analysed research into stigma, and found the lack of a clear definition of what is meant by stigma, the frequent confusion of stigma with discrimination and unclear distinction between the types of stigma that exist made it difficult to compare the findings of the papers reviewed [68].

A further barrier to testing found in five Grade III European studies is lack of information about where to obtain a test, what the results might mean, and the facts of HIV disease [66]. This supports the conclusion in two studies that HIV prevention and testing messages, including the benefits of knowing HIV status, need to be tailored to the cultures of those receiving the messages [69,74,75]. A survey of Black African migrants living in the UK reported concerns about where to obtain an HIV test; many were not aware that an HIV test can be obtained without the need of referral [81].

In migrant populations confidentiality concerns were seen as particularly relevant in three Grade III studies [66]. Studies of Black Africans living in the UK found concerns about disclosure if they were seen accessing HIV or STI clinics, or through healthcare providers disclosing their status to community members [73,82].

Barriers at the healthcare provider level

Evidence included: 13 Grade III studies

Healthcare providers are the gateway to HIV testing. Evidence has shown that barriers exist at the provider level which could hinder efforts to increase HIV testing. Barriers consist primarily of discomfort when approaching the subject of HIV, lack of training to increase healthcare providers' competence in conducting HIV testing, lack of knowledge on the part of healthcare providers about local HIV prevalence, symptoms of undiagnosed HIV infection and local guidance and policy on HIV testing, and logistical barriers such as cost and time constraints and cumbersome consent procedures.

Such barriers can contribute to missed opportunities to test, leading to late diagnosis of HIV infection. Evidence of missed opportunities for diagnosis by healthcare providers has been demonstrated in several retrospective reviews, with between 50% [83] and 100% [84] of diagnosed individuals having had clear triggers for HIV testing (either a documented risk factor or an HIV-related illness) documented in their medical records by a healthcare provider in prior consultations without the diagnosis being made. In the UK, the medical attendance histories of a high-risk population of Black Africans who had tested HIV positive were examined. HIV testing was not broached for 82% of HIV-infected individuals who accessed primary care services in the year prior to their HIV diagnosis [71].

Lack of knowledge or information regarding HIV, including reasons for testing, symptoms of HIV infection, and local HIV testing policies, were found to be a barrier to testing in eleven Grade III studies. Previous qualitative studies have highlighted the importance of clinician recommendation in influencing uptake of testing [71,85]. Studies of HIV testing in antenatal clinics in the UK found that the patients of midwives who doubt the benefits of HIV testing were less likely to accept an HIV test when offered [86,87]. Audits of healthcare providers' adherence to existing HIV testing guidance varies widely, with only 3% to 57% of healthcare providers offering HIV tests in accordance with relevant national HIV testing guidance [88–91]. A study of German nurses found gaps of

knowledge, including AIDS immunopathology or the symptoms of the disease [92]. A study of nurse's knowledge about risky sexual behaviour conducted in Finland, Estonia, and Lithuania found that low knowledge about HIV-related risk behaviour was associated with higher age, and having no previous experience nursing an HIV-infected individual [93]. Failure to offer a test may be a result of inappropriate or insufficient training for how to conduct HIV testing. A survey among midwives in one antenatal clinic and a number of postnatal wards in a low-prevalence area in the UK showed that while all respondents agreed that antenatal HIV testing is important, 44% felt that their training had not adequately prepared them for understanding the challenges of HIV in pregnancy and delivery [94].

Healthcare providers' discomfort or anxiety around HIV has been noted as a key barrier to offering HIV testing to individuals in three Grade III studies. A survey among general practitioners in the UK reported that raising the issue of HIV testing in primary care was associated with a high level of anxiety. The majority of GPs avoided rather than promoted the issue of HIV testing, even in high-risk groups [95]. A UK study of HIV testing strategies in antenatal services found that the uptake of an HIV test depends more on the attitude of the individual midwife than the method of offering the test and time spent on pre-test counselling [87]. Barriers to testing have been reported among clinicians treating HIV indicator diseases, including discomfort with HIV and lack of time and skills required for pre-test counselling [96].

Barriers at the institutional level

Evidence included: 2 Grade III studies

When HIV testing policies and strategies are not in place or poorly implemented, this presents a barrier to testing. The impact of antenatal HIV testing strategies on the uptake of the test has been demonstrated in the UK throughout the 1990s. At the time when most maternity units in the UK provided testing only at the explicit request of the individual woman or for selected groups of women perceived to be at higher risk, detection rates were low, resulting in most HIV-infected women remaining undiagnosed at delivery [97]. In addition, it was shown that the national policy recommending universal testing in high-prevalence areas was not being implemented. The offer of the test was an exception rather than the norm and the uptake was very low, with the maternity unit as the strongest predictor. As a consequence, targets were set by the government in 1999 to introduce universal offer of HIV testing to pregnant women, with targets set at 50% by the end of 2000 and 90% by 2002 [98], resulting in significant improvements in testing within a few years [99]. By 2004, 96% of all pregnant women in the UK were tested for HIV, resulting in the diagnosis of 92% of HIV infections before delivery; this level of testing has been sustained [22].

Lack of funding, staff and office space, as well as lack of training of the staff were identified as main barriers to offering on-site HIV testing and counselling in drug treatment programmes in a Grade III study from Hungary [100]. A Grade III UK study found that lack of political will, advocacy, as well as financial and human resources, were factors contributing to late presentation and poor utilisation of HIV health and social care services by African migrants [73].

3.3 Strategies to increase HIV testing

The objective of this guidance is to define the uptake, quality and effectiveness of HIV testing interventions. The following are strategies that have been designed to overcome barriers to testing and are measured by these criteria.

Media campaigns

Evidence included: 1 Grade IB study, 3 Grade IIB studies, 2 Grade III studies

Many European countries have a long history of conducting campaigns to raise awareness of HIV and increase HIV testing. The earliest HIV awareness campaigns targeted MSM and were organised by non-governmental and community-based organisations, and used informal information sharing, education programmes and heavy press coverage [101]. These campaigns lacked structured design and evaluations; however retrospective studies show a temporal relationship between the early HIV awareness campaigns and a rapid decrease in HIV transmission among MSM [101].

Early HIV campaigns were used to raise awareness with knowledge and attitude measures as the most common outcome measures, while later campaigns were designed to affect behaviour change [102]. However, with the majority of campaigns having weak outcome evaluation designs, it has been difficult to estimate the impact of HIV campaigns [102]. A Grade IIB systematic review of HIV campaigns showed that more recent campaigns have used quasi-experimental designs with a control group to evaluate the effects of the campaign (30% of studies post-1998 compared to 17% of studies pre-1998) [103].

A Grade IIB review of the literature found that most campaigns report a positive impact on knowledge and attitudes post-campaign [103]. However, in most cases, studies lack a control group for comparison making the change in knowledge and attitudes, or lack thereof, difficult to interpret. For example, a lack of an increase in

knowledge post-test in one study may be indicative of an HIV 'information saturated' audience, whereas in others it may reflect campaign inadequacy.

Behaviour change campaigns have been better evaluated. The same review found that eight out of ten studies with quasi-experimental designs showed statistically significant positive effects on behaviour or behavioural intentions [103]. This is consistent with an existing Grade IIB meta-analyses suggesting that HIV campaigns can have behavioural impact [104].

There is good evidence that use of mass media in HIV testing campaigns increases HIV testing uptake. One grade IB meta-analysis of fourteen studies in developed countries (seven of which from the UK) that compared media interventions with a control in relation to promotion of HIV testing found that all individual studies results showed positive impacts of mass media on HIV testing. This was confirmed by statistical pooling of effects which showed a significant initial impact of mass media on the uptake of HIV testing, but non-significant long-term impact on uptake of HIV testing [105]. A Grade IIB review of 29 media interventions in developed countries (including 17 from the UK and one from France) reporting outcomes of HIV testing campaigns found an average 53% increase in the number of HIV tests after implementation of the media campaigns. Of the eleven media interventions reporting HIV seropositivity there was an average reduction of 15% detected positive as a result of the campaign [106]. Mass media can be effective in increasing the uptake of HIV testing and diagnosing infections, however a reduction in HIV seropositivity after a campaign suggests mass media may disproportionately attract low risk individuals.

Social marketing is one of several identified strategies for scaling up HIV testing services [107,108]. Social marketing is the adaptation and systematic application of commercial marketing techniques to achieve specific behavioural change for social goals. Initially used to increase condom sales in developing countries, social marketing is increasingly used in targeted HIV testing campaigns as a strategy for behaviour change, though data from Europe is lacking [109–112]. Only two Grade III studies have reported change in HIV testing rates as an outcome and both found no significant effect. One Australian social marketing campaign targeting MSM failed to increase HIV testing, although this may be explained by high baseline rates of HIV testing (60% had tested in the past 12 months) as well as a limited budget [113]. Another social marketing campaign from the United States which targeted African-American women found a non-significant increase in the total number of tests performed but this association could not be directly attributed to the campaign [111]. Both studies used national or state level surveillance data to measure HIV testing rates.

Importantly, countries with concentrated epidemics have increasingly targeted HIV campaigns towards high-risk populations, as opposed to the general population, in order to increase HIV testing [106]. One review found that prior to 1998 only 41% of HIV campaigns were targeted, compared to 97% of campaigns after 1998 [102,103].

Normalising HIV testing

Evidence included: 13 Grade III studies, 1 Grade IV study

Prior to the mid-1990s and the availability of effective therapy, uptake of HIV testing varied widely, even within similar healthcare settings. Most testing guidelines recommended offering HIV testing to individuals with 'high-risk' behaviours. While targeted testing of 'high-risk' individuals accurately detects a high number of infections, a significant proportion of HIV infections are missed due to individuals being deemed 'low-risk'. A Grade III systematic review of 62 studies in the United States published between 1985 and 1996 reported that uptake of voluntary HIV testing varied between 11% and 91% amongst those offered a test; most of these studies targeted 'high-risk' individuals [114]. A large Grade III retrospective study from the United States showed that risk assessment meant that 20% to 26% of HIV-infected individuals reported no risk factors [115]. This is supported by seven Grade III studies in a variety of settings where 7% to 51% of HIV infections would not be identified by targeted testing [116–122].

With the advent of effective antiretroviral therapy, attention was turned to rates of late diagnosis and estimates of undiagnosed infection. A Grade IV article made the argument that earlier and more widespread diagnosis of HIV infection would maximise benefits of therapy and improve life expectancy [123]. This led to policy makers in the United States to recommend voluntary HIV testing as part of routine medical care in areas with HIV prevalence of 0.1% in order to 'normalise' testing. Four Grade III United States studies in high-prevalence settings demonstrated increased seropositivity rates following the implementation of routine voluntary HIV testing [124–127].

Following the United States' recommendations, policy makers have focused on strategies to detect HIV before the late stages of infection. This has included exploring technologies to make HIV testing quicker and more acceptable to patients, expanding HIV testing in a wide range of healthcare and non-healthcare settings, and various forms of the pre-test counselling and consent procedure. Increasingly, countries are adopting a policy of universal offer of HIV testing in some or all healthcare settings in combination with risk-based testing [60,128,129].

Training healthcare providers

Evidence included: 1 Grade IIB study, 17 Grade III studies

Appropriate training and resources can motivate healthcare providers to offer an HIV test. The training needs of healthcare providers can be classified into two areas, as identified by twelve Grade III studies evaluating factors associated with low test offer or studies gauging attitudes of healthcare providers towards HIV testing:

- Knowledge needs: including local HIV prevalence, HIV testing guidance recommendations, risk factors and symptoms of HIV infection [85,88-91,130]; awareness of the presentation of acute HIV infection [131]; and modes of HIV transmission [92,132].
- Skills needs: including giving positive diagnoses [90,133] and better documenting of risk factors, symptoms or examination findings that could indicate possible HIV infection [83,84].

Additionally, healthcare providers' concerns regarding logistics and resources such as the time required, a burdensome consent process, pre-test counselling requirements, the availability of appropriate follow-up for patients and support for staff, and competing priorities may lead to initial resistance or reservations about routinely offering HIV testing, as found by one Grade IIB and seven Grade III studies [84,88-90,130,134-136].

These issues continue to dominate the discourse on the feasibility of HIV testing in a wide range of healthcare settings; however one Grade IIB and two Grade III studies have shown significant improvements in perceptions of feasibility and acceptability among healthcare providers after training and a short period of time to get used to testing [136–138].

It is also important to healthcare providers that occupational health precautions are in place to prevent occupational exposure to HIV. Two grade III studies from Europe highlight the importance of ensuring that infection control procedures are documented and enforced and that adequate resources are available to allow staff to take the necessary steps to protect themselves [132;139]. To reduce stigma associated with healthcare provider's fear of occupational exposure to HIV, training in exposure risk and HIV transmission routes should be structured and coordinated, using evidence-based teaching methods [132].

Confidentiality of both the act and result of the HIV test is a key principle in the WHO European Region policy framework on scaling up HIV testing and counselling and WHO/UNAIDS provider-initiated testing [140;141]. Breach of patient confidentiality presents ethical and legal dilemmas and causes a breakdown of trust between patient and healthcare provider. Healthcare providers must maintain patient confidentiality, as in any healthcare setting, and it is important to communicate this. In light of this policy, no studies have been conducted evaluating the effects of assuring confidentiality on HIV testing rates, although qualitative studies have indicated that fear of breach of confidentiality is a reason for declining HIV testing.

Simplified consent procedure

Evidence included: 3 Grade III, 8 Grade IV studies

Informed consent is an ethical and, in most EU countries, legal requirement for HIV testing. Despite this, there is evidence that HIV tests are being carried out in Europe without explicit consent of the patient [142;143], and this occurrence is likely to be understated in the published literature. A key principle in the WHO European Region policy framework on scaling up HIV testing and counselling is that HIV testing must always be done with informed written or oral consent and adequate pre-test information or counselling [140]. The current notion of best practice, included in the WHO/UNAIDS testing guidance maintains that it should be clear that testing is voluntary and the patient can refuse consent without negative consequences [141]. Verbal or written information provided should include the reason for testing, the benefits and risks of testing to the individual, and details on how a positive or negative result will be managed. Individuals should be given the opportunity to ask questions, before accepting or declining testing.

There is evidence that requiring written consent, as opposed to verbal consent, is a barrier to testing. In a retrospective Grade III study from the United States, HIV testing rates in states with statutes requiring written informed consent were compared to states without such statutes, and found that written informed-consent statutes are associated with a 12% reduction in HIV testing [144]. There is retrospective evidence from two Grade III studies that verbal consent is an acceptable substitute for written consent, and results in higher rates of testing [144–146]. In one observational study from the United States, elimination of written consent requirements resulted in a 44% increase of HIV testing in a hospital setting, with the highest risk groups benefiting most reflecting a 67% increase in positive HIV tests [145]. Another study analysed testing rates in New York State before and after the removal of a written consent requirement, and found a 31% increase in testing [146]. This data suggests verbal consent is adequate and a separate consent form for HIV is not required.

There exists some debate in the literature about the need for specific consent for HIV testing, and the ethics of accepting implied consent. Eight Grade IV opinions and case studies have been identified. Some argue that requiring specific consent amounts to 'HIV exceptionalism': treating HIV differently to other diseases [123,147–149]. They claim that this requirement presents a barrier to testing, resulting in lower rates of HIV testing,

especially in primary care settings [150]. To this end, some suggest using blanket consent for a battery of diagnostic tests that include HIV would remove barriers and 'normalise' the HIV testing process [151]. However, others continue to support a more conservative approach that includes requiring patient's specific consent before HIV testing in order to ensure patient autonomy and self-determination [152,153]. Further ethical discussion on this topic is warranted.

Alternatives to pre-test counselling

Evidence included: 6 Grade IB studies, 1 Grade IIB study, 8 Grade III studies

Traditionally, standard pre-test counselling is carried out prior to HIV testing, and consists of interactive process whereby an individual risk assessment is undertaken and specific HIV risk behaviours are identified in order to deliver a tailored prevention message. However, evidence supporting this approach is lacking. Despite evidence that standard pre-test counselling with testing has been shown to reduce subsequent risk behaviours in HIV-positive individuals, it is not possible to determine whether this reduction is due to counselling or the diagnosis itself [38,39]. However, the causal link between counselling and behaviour change is weakened by prospective cohort studies showing no reduction in risky behaviour in individuals testing HIV negative in regular practice [38,39]. In a controlled scenario, pre-test counselling may influence behaviour change in HIV-negative individuals as reported in one Grade IB randomised controlled trial of two 20 minute counselling sessions of motivational interview, resulting in a 30% to 40% reduction in risk behaviour [154]. However, this quality of pre-test counselling may not be practical and especially difficult to achieve in busy settings or for healthcare providers who are not HIV specialists offering HIV tests.

The WHO Europe guidelines propose that providing brief pre-test information, rather than counselling, may make HIV testing more feasible in some settings [140]. Brief pre-test counselling takes roughly half the time of standard pre-test counselling (7–10 minutes compared to 15–20 minutes), resulting in a substantial reduction in counselling costs [65]. Knowledge and sexual risk behaviour scores post-test were similar between individuals assigned to standard and abbreviated counselling in one Grade IB randomised control trial [43]. Another Grade IB randomised control trial in the antenatal setting showed that knowledge scores were lower among women assigned to abbreviated pre-test counselling compared to standard pre-test counselling, however knowledge scores were high among women in both arms of the trial (78% vs. 84%). The study showed no difference in decision to accept HIV testing between interventions, but suggests that abbreviated counselling does not compromise patient decision-making or satisfaction regarding HIV testing and is easier to implement systematically [155].

In settings where HIV testing is routinely offered to all individuals, such as STI clinics, two types of testing strategies are commonly used: 'opt-in' and 'opt-out'. Under the 'opt-in' approach, the HIV test is dealt with separately from other tests and is accompanied by pre-test information and informed consent, whereas the 'opt-out' approach offers the HIV test alongside other blood tests. Adoption of an 'opt-out' approach to HIV testing is increasingly used to improve uptake of HIV testing, with nine of sixteen European Union countries indicating that they employ 'opt-out' testing in the antenatal setting; five of these countries also employ 'opt-out' testing in other settings, such as STI clinics or TB clinics [156,157]. There is good evidence that 'opt-out' testing identifies HIV-infected individuals earlier than targeted, risk-based screening methods:

- A Grade IB randomised controlled trial of HIV testing strategies in antenatal showed that 'opt-out' testing was acceptable, did not cause anxiety, and had a higher uptake than other methods [87].
- One Grade IIB study from the United States reported that introducing an 'opt-out' testing approach from 'opt-in' testing in the antenatal setting increased uptake from 75% to 88% [158].
- Eight Grade III studies comparing 'opt-out' testing to other HIV testing strategies ('opt-in' or targeted testing) found increased uptake of HIV testing through the 'opt-out' testing approach [159–166].

The creative use of video technology is one strategy to overcome barriers in the provision of HIV counselling and testing. This intervention is useful in busy healthcare settings, such as acute care services. One Grade IB randomised controlled trial from the United States found comparable knowledge scores among those assigned to watch a pre-test counselling video compared to those assigned to standard pre-test counselling (85.3% video arm versus 79.7% standard arm) [167]. Among those viewing the video, all but one went on to consent to HIV testing, and 92% felt they had received enough information from the video to give informed consent [167]. A Grade IB randomised non-inferiority trial in the United States found that video counselling was an acceptable substitute to pre-test information delivered by an HIV test counsellor based on results of a post-counselling knowledge and understanding questionnaire [168]. An educational video may be a feasible alternative for providing testing information when trained staffs are unavailable for direct, interactive counselling.

Alternatives to post-test counselling

Evidence included: 1 Grade IB study, 3 Grade III studies

Post-test counselling occurs after an individual has had the HIV test and includes receipt of test result alongside HIV prevention information. Arrangements for communicating the results are agreed at the time of testing, particularly if the test is being performed in an outpatient or acute-care setting. HIV-negative individuals may

receive information around risk reduction or behaviour change and if still within the window period after a specific exposure, the need for a repeat HIV test is discussed. HIV-positive patients are given details of local specialist services and have established a clear pathway for onward referral prior to receipt of result. More detailed post-test discussion (including assessment of disease stage, consideration of treatment, and partner notification) is performed by an HIV specialist.

Standard HIV testing takes up to two weeks for a result, so an appointment must be made for individuals to return for test results. Studies have found that 10% to 55% individuals accepting standard testing do not have a post-test counselling session or fail to return for test results [169–171]. Furthermore, two studies of routine testing in acute care centres found that 18% to 26% of HIV-infected patients did not receive their positive results [124,125]. Although most (79% to 93%) HIV-positive patients are eventually located; a median of 12 days was required to locate HIV-infected subjects who failed to return [169]. Considerable time and effort is required to find and notify those subjects testing HIV positive who fail to return.

Expansion of HIV testing into more healthcare settings has inspired the use of alternative methods to streamline the testing and counselling process. One Grade III study from an STI clinic in the United Kingdom allowed low-risk individuals to receive test results by telephone appointment or by post [172]. Only negative results are given by post and individuals with positive results are recalled to clinic or counselled over the telephone. A similar Grade III study in a UK STI clinic reported that all 16 low-risk individuals with positive results who were originally planned to receive results by post were successfully located and recalled for post-test counselling [173].

In settings where staff time and resources are limited, such as acute care and outreach settings, video has also been proposed as a means of communicating post-test counselling information. One Grade IB randomised controlled trial assigned individuals to either a standard post-test counselling session or watching a 15-minute video prior to receiving results. The video covered post-test information such as prevention strategies, including condom use, interpretation of HIV results, partner notification, and issues of domestic violence. Mean post-intervention knowledge scores were higher in the video group (76% vs. 69%) and the authors concluded that the video was not inferior to a standard post-test counselling session [174].

Meeting the needs of HIV-positive patients during the post-test counselling session is important to secure trust and ensure linkage into medical and social care. A Grade III qualitative study of patient experience after receiving a positive HIV result asked, 'What are the most important parts of the counselling session when people are told that they have HIV in the clinic?' Of the sixty-six interviewees, 43 said something about the compassion and emotional support of the counsellor; 26 mentioned HIV-related education or information that was important to them; 11 mentioned referrals for both medical and social services; nine mentioned safe sex or partner notification; and seven said that confidentiality of the session was important [175].

HIV testing technologies

Evidence included: 1 Grade IB study, 1 Grade IIA study, 8 Grade III studies

EU directives and regulations set down the specifications demanded for in-vitro diagnostic tests for the detection of HIV infection that can be sold and used for human diagnostics on the internal market [176,177]. Using a combination of a screening test with a confirmatory test for verification of initial positive results is always required for diagnostic testing of HIV infection.

The use of a combination enzyme-linked immunoassay (EIA) antibody-antigen screening test (frequently referred to as 4th generation EIA), followed by a confirmatory test in the form of a Western blot or line immunoblot assay is the current gold standard for diagnosing HIV infection in most circumstances [178]. The screening test has a required sensitivity of 100% and specificity of 99.5% [177]. With the confirmatory test, the chance of getting a false-positive in a low-prevalence setting is reduced to a very low level [179]. The method is relatively inexpensive in large turnover clinical laboratory settings and has been technologically refined to high reliability, if good laboratory practice standards and quality management systems are followed.

Disadvantages to this method include the need for venipuncture and requirement for a follow up visit one to two weeks after the initial visit to receive the test result and referral into care. Up to half of persons tested at publicly funded clinics do not return to receive their HIV test results and some may be less likely to accept testing if a return visit is required [171,180]. Stress and anxiety are associated with the delay in receiving the test result [181].

The use of more convenient, less invasive HIV tests could improve HIV testing acceptability and uptake. Rapid HIV tests (also known as point-of-care tests) are single-use disposable HIV devices that directly test whole blood or oral fluid. Results are available within 30 minutes of testing. Sensitivities of rapid tests range from 98%-100% with specificities around 99% [182–185]. Rapid testing kits are more expensive than the EIA laboratory assay, but are roughly equivalent when laboratory time and labour are included [65,184]. The accuracy of some brands of rapid tests is slightly lower than EIA tests, which can result in false-positive initial test results. Two large studies performed in acute-care settings and antenatal settings found false-positive rates of between < 0.01% and 3.1% [186,187]. Laboratory test must be performed for all positive rapid test results.

Rapid tests are advantageous in settings where venipuncture is not possible or where quick turnaround of test results is desirable, for example in busy clinical settings or community testing sites.

- A Grade IB randomised controlled trial in the United States found 31.0% of individuals assigned to standard testing received their results, compared to 79.8% of individuals assigned to rapid testing [43].
- A Grade IB trial of outpatients and inpatients randomised to a rapid versus a standard HIV test found a trend towards a higher rate of test uptake in individuals randomised to a rapid HIV test versus standard testing (59% versus 41%) [188].
- A Grade IIA meta-analysis of alternative HIV testing methods showed that rapid testing significantly increased receipt of test results in all settings evaluated, with the largest effect sizes in acute care settings, STI clinics, and outreach settings. More individuals assigned to rapid testing received their results compared to individuals assigned to standard testing (95% vs. 43%) [189].
- Two Grade III studies have found rapid HIV testing to be acceptable and feasible to use in busy clinical settings and community testing sites [190,191].
- One Grade III study found high acceptability of rapid testing among 150 patients being treated for substance abuse, all of whom chose an oral fluid rapid test over a standard blood test [192].

Rapid tests eliminate the need for a second visit to receive negative results. However, with one visit there is less opportunity to impart knowledge and prevention messages. Anxiety regarding this has been assuaged by one Grade IB randomised controlled trial in an STI clinic which found no difference in STI incidence at 12 months post-test between individuals assigned to rapid testing and individuals assigned to standard testing and counselling [42].

It is generally recommended that HIV testing be carried out in a healthcare setting; however this can be a barrier to testing. One Grade III survey found that while 62% of respondents would prefer to be tested for HIV in a doctor's office or clinic, 26% preferred to be tested at home [193]. Home sampling kits do not require attendance at a healthcare setting and are a convenient, speedy, and anonymous option. Home sampling requires a saliva or blood sample taken at home and sent to a laboratory for testing. An individual is then notified within a few days of the result; positive results are given by telephone but negative results may be sent by email. Telephone-based counselling is provided for reactive results. Four Grade III studies have evaluated home sampling as a feasible HIV testing approach. One study from the United States found that the sensitivity and specificity obtained with finger-prick blood spot samples using a home testing kit were 100% [194]. More than 98% of participants in two studies obtained adequate samples for testing [194,195]. One large study from the United States found high rates of receipt of result, with 95% of 174,316 persons submitting home samples calling for results [196]. Disadvantages to home sampling kits include lack of pre-test information and high cost [197]. Further research is needed to assess the acceptability and reliability of home testing for HIV, the impact of home sampling and home testing on risk reduction behaviours and access to care.

HIV NAT assays (nucleic acid tests used mainly to measure viral load) are not recommended as screening assays in developed countries because of the possibility of false-positive results. Similarly, urine HIV tests generally appear less accurate than standard testing and are not in widespread use [198,199]. Home testing is an approach which involves a person conducting a rapid HIV test with a blood or saliva sample and interpreting results in their home. At present, no home testing kits are licensed for sale in Europe and it is illegal in most countries to sell home testing kits to the public, due to the risk of individuals performing their test, or interpret their results, incorrectly, especially without post-test counselling and the risk of false-positive results associated with rapid tests. Additionally, a positive rapid test must be confirmed with a laboratory test, requiring individuals to self-refer to healthcare services.

Laboratory quality assurance

Evidence included: No studies identified

No studies have been identified which evaluate the independent impact of quality assurance in the laboratory on the effectiveness of HIV testing. However, all laboratories undertaking any diagnostic HIV testing should have a well-functioning quality assurance programme which follows recommended international HIV testing guidelines and relevant national HIV testing algorithms. For rapid testing, the WHO has issued guidelines for quality assurance [200]. National guidelines for applying a minimum standard of quality assurance for diagnostic/laboratory testing are essential to ensure high quality practice and methodological standardisation and reliability. Laboratories should be able to demonstrate satisfactory quality control and have full accreditation status. All laboratories should have HIV confirmatory assay algorithms in place to allow timely return of results. This may involve referring samples to specialist virology laboratories or national or international reference laboratories.

Testing frequency

Evidence included: 7 Grade III studies

The optimal frequency of testing will vary depending on the incidence and the prevalence of undetected HIV infection in the group being tested according to one Grade III study [201]. No studies evaluating the optimal frequency of HIV testing in populations with low or high prevalence were reported.

Six Grade III studies from the United States, Australia and UK have attempted to characterise repeat testers attending HIV and STI clinics. The studies report the following:

- Between 32% and 51% of HIV and STI clinic attendees were repeat testers. Older age, multiple partners, and returning for post-test counselling were associated with repeat testing [202,203].
- Regarding risk behaviour, a United States study found repeat testers practice higher risk behaviours and higher incidence of HIV compared to first-time testers [204].
- Conversely, no differences were found in the frequency of unprotected sex between repeat and first-time testers in a population of UK STI clinic attendees. However, when stratified by risk group, an association between high rates of unprotected sex and repeat testing was seen in MSM [203].
- Among MSM, repeat testers were more likely to report recent unprotected sexual intercourse; they also report a high number of recent sexual partners compared with first-time testers [205,206]. Over 75% of repeat testers who seroconverted acquired HIV within one year of their last test [205].
- An audit of repeat testing among MSM in Australia, where annual testing of MSM is recommended, found only 35% MSM having an annual test [206].
- Among repeat testers, HIV acquisition between tests was highest among MSM and those with a history of incarceration [202].
- A UK study found that recall of MSM diagnosed with a bacterial STI detected a high incidence (2%) of newly acquired HIV infection at three months. The authors conclude that recall of MSM diagnosed with bacterial STIs may result in early identification of recent HIV infection [207].

The authors of one Grade III study propose some recommendations about the frequency of HIV testing in certain populations, including biannual HIV testing among MSM practising anal intercourse, and less frequently for heterosexuals, IDUs, and MSM not practising anal intercourse [204].

A synthesis of national HIV testing guidelines found that United States, Australia, UK, Norway and France include details on frequency.

- The United States recommends annual testing of high-risk individuals including IDUs and their sex partners, commercial sex workers, sex partners of HIV-infected persons, and MSM or heterosexual persons who have had more than one sex partner since their most recent HIV test.
- The UK, Australia and France have instituted similar policies on annual testing of a number of high risk populations.
- Norway recommends annual testing of MSM only.

Discrepancies between the evidence and recommendations suggest that further studies are needed to assess the optimal frequency of HIV testing and to assess the effectiveness of implementing recommendations for the frequency of HIV testing.

Ensuring access to care

Evidence included: 12 Grade III studies

The purpose of any HIV testing programme is to bring infected patients into the healthcare system for ongoing care and monitoring of their HIV infection. Failure to do so undermines the basis of the testing programme. Early initiation of medical care subsequent to diagnosis is one of the primary goals of improving the effectiveness of HIV testing strategies. Unfortunately, some patients who receive a positive HIV test result may delay medical care or not receive care at all. Four Grade III studies from the United States found that 17% to 29% of patients had delayed entry into care for at least three months [46,208], and 11% to 39% delayed it for at least 1 year [46,209,210]. One Grade III study of rapid testing found that entry into care within six months ranged from 100% in an STI clinic to 22% in a prison [211].

Two Grade III studies reported reasons for delayed entry into care. In one United States study, of newly diagnosed patients who had not yet linked into medical care after diagnosis (18% of interviewees), reported reasons for not attending include never receiving a referral, denial of diagnosis, feeling well and therefore feeling medical care is not needed, fear of recognition by others at an HIV clinic, religious reasons, and lack of transportation [175]. Another United States study identified factors associated with delayed entry into care, including male gender, younger age, injecting drug use, testing positive anonymously, and having a positive diagnosis from the first HIV test [212].

Pathways into care must be established, especially in busy settings such as acute care and non-medical settings such as the community. The CDC and British HIV Association recommend that an individual testing HIV positive for the first time be seen by a specialist at the earliest possible opportunity, generally within two weeks of receiving the result [129,213].

Rapid testing has been associated with higher entry into care through increased knowledge of HIV status in three Grade III studies. Three rapid HIV testing programmes from acute care settings in the United States have demonstrated high rates of linkage to care, ranging from 79% to 91%, with an average time from diagnosis to first follow-up appointment of 14 days [214]. All three programmes had HIV counsellors on site and appointment slots made available at local HIV clinics for patients with preliminary positive results in the acute care setting. All confirmatory tests were sent while the patient was still in acute care, and results were available at the time of the follow-up appointment. When an individual is diagnosed with a positive rapid HIV test, the need for follow-up is also important to ensure that confirmatory results are provided [215]. In one study of rapid testing in an acute care setting, individuals with positive results were informed and counselled by a healthcare provider and walked to the HIV clinic in the hospital [174].

Other tactics employed by two Grade III studies to increase rates of entry into care include sending reminders to patients before their first follow-up appointment, offering the patient the opportunity to speak with an HIV provider at the time of diagnosis, and ensuring clinic appointments within 24 hours of diagnosis [215,216].

3.4 Testing approaches by setting

Sexually transmitted infection (STI) services

Evidence included: 1 Grade IB, 10 Grade III studies

Sexually transmitted infection (STI) services offer HIV testing due to the strong link between the infection with sexually transmitted diseases and increased transmission of HIV infection [217,218].

The very first recommendation for HIV testing in a population was for routine testing of individuals seeking treatment for STIs (CDC 1987). A survey of European testing policies found that 17 out of 18 (94%) responding European Union countries offered HIV testing routinely to STI clinic attendees, Poland being the only exception [157]. European guidelines for HIV testing of STI clinic attendees have been issued jointly by the European Office of International Union against Sexually Transmitted Infections (IUSTI) and the WHO Regional Office for Europe [219]. Over the years, several strategies for identifying HIV infection in STI clinic attendees have been used.

Risk-based HIV testing is a selective testing strategy whereby individuals with reported risk factors for HIV, such as sex between men or injecting drug use, are offered HIV testing and counselling. This may also include high-prevalence demographic groups, such as individuals from sub-Saharan Africa. However, two Grade III studies have shown that risk-based testing may result in missed opportunities to diagnose a significant proportion of HIV infections. A prospective study from an STI clinic in the UK found 7% diagnoses would have been missed through a broad risk-based selective testing strategy [220]. Similarly, a retrospective study from a United States STI clinic evaluated targeted testing of two different populations: only persons with reported risk factors versus those with reported risk factors plus individuals from high-prevalence demographic groups. The study found that using only reported risk factors to indicate HIV testing would have resulted in 74% missed diagnoses, whereas the broader risk-based strategy would have resulted in only 8% missed diagnoses [221].

'Opt-in' testing strategies that offer HIV testing routinely to all STI clinic attendees have been trialled in three Grade III studies. A prospective study of STI clinic attendees in Amsterdam compared testing uptake and undiagnosed infection among high-risk heterosexuals before and after a policy of 'opt-in' testing to all STI clinic attendees was implemented in 1999. The study found that testing uptake rose from 13% in 1996 to 56% in 2004 [78]. However, a retrospective study from the UK found that a high proportion [222] of STI clinic attendees refused an HIV test under an 'opt-in' strategy, and those at highest risk were most likely to refuse the test, such as belonging to a high-risk demographic [223] and an STI diagnosis [79]. Likewise, a prospective study from the United States found that 37% of STI clinic attendees refused a test, and an unlinked anonymous survey found that those refusing had a higher HIV seroprevalence than those that accepted [117].

Three Grade III studies have reported that an 'opt-out' testing approach is associated with higher rates of HIV testing compared to 'opt-in' or risk-based testing. A retrospective review of the impact of HIV testing strategy changes in STI clinics in the Netherlands reported an increase in testing uptake from 88% to 98% within one year of a policy change to 'opt-out' from 'opt-in' testing [159]. One cross-sectional survey from Scotland showed an increase in testing uptake among MSM at the population level from 50% to 58% after initiation of a national 'opt-out' testing policy [224]. A study from the UK audited HIV testing offer and uptake in three STI clinics found a small increase in testing uptake from 68% to 72% among 'low-risk' individuals after implementation of an 'opt-out' policy, however this resulted in no additional HIV diagnoses [161].

Rapid testing in STI clinics has reported high acceptability among STI clinic attendees in one Grade IB and two Grade III studies. A multi-site randomised controlled trial from the United States compared acceptability of rapid

testing versus standard testing and found uptake of HIV testing to be higher among STI clinic attendees offered rapid testing compared to standard testing (99% versus 69%) [42]. For a retrospective study from the United States, STI clinic attendees were given a choice of standard or rapid HIV testing. Of the 80% of STI clinic attendees who agreed to HIV testing, 87% chose rapid testing and 13% chose standard testing. Nearly all (99%) of the rapid testers received their results and post-test counselling on the same visit, compared to only 84% of standard testers receiving their results after two weeks [225]. Access to care amongst those newly diagnosed was also reported in this study which found that all newly diagnosed rapid testers attended their first HIV clinic appointment, with the exception of one individual who died [225]. One prospective study from the UK surveyed test method preference among individuals accepting rapid testing in four STI clinics. Overall, 85% were in favour or receiving same-day HIV test results, and 40% reported they would have tested sooner had they known rapid testing was available. Individuals accepting rapid oral testing agreed that the oral mouth swab procedure was easy and comfortable [226].

Harm reduction services

Evidence included: 1 Grade IB study, 3 Grade III studies

Harm reduction services, including drug treatment programmes and needle and syringe programmes (NSPs), present an opportunity to test injecting drug users (IDUs). IDUs that share needles are at risk of infection through exposure to contaminated needles as well as through sexual contact. Furthermore, IDUs are a particularly vulnerable population with a high burden of medical and psychological co-morbidities and often chaotic lifestyles [227]. HIV testing in harm reduction services can reach a high proportion of IDUs in Europe as every country in the Europe Union has an NSP implemented and all countries include some form of drug treatment programme with high coverage rates [228]. However coverage varies by country, particularly in the eastern part of Europe (where rates of injecting drug use are highest), from 15% in Slovakia to 68% in Lithuania [228]. Furthermore, HIV testing in harm reduction services only reaches injecting drug users who choose to access such services.

Use of HIV tests that do not require venipuncture has been hypothesised as more acceptable to injecting drug users. This was supported by a Grade IB randomised controlled trial in an outreach clinic at a NSP in the United States which reported that 12% of IDUs accepted and completed testing on days when oral fluid testing was offered, compared to 5.2% on days when standard testing was offered. Receipt of results for both tests was low, due to poor attendance at follow-up appointments [229]. A Grade III prospective study from a residential drug treatment programme in the United States found that all 150 inpatients accepting testing chose an oral fluid test over a standard serum test. Only 65% of patients received their results due to the 2–4 day delay in receiving results, by which time more than half the patients had left the residential programme [192]. This data illustrates the difficulties of requiring two separate visits for the standard HIV test procedure in IDUs.

Rapid testing is a strategy which has been trialled in IDUs in order to increase receipt of results as reported by one Grade IB and two Grade III studies from the United States. This strategy has effectively increased knowledge of status, however there is evidence that IDUs may not find rapid testing acceptable, particularly if requiring venipuncture or finger-prick. The previously described randomised controlled trial compared rapid testing (requiring venipuncture) with oral fluid testing and standard testing and found that IDUs preferred oral fluid testing to rapid and standard testing. However 83% of rapid testers received their results compared to 60% of oral fluid testers and 56% of standard testers [229]. A descriptive study offering both rapid test (requiring finger-prick) and standard testing at a mobile testing site found that test preference was similar between the two tests (57% chose rapid test and 43% chose standard test), and individuals who reported recent drug use were less likely to choose a rapid test compared to another risk group, African Americans. However, 93% of rapid testers received their results compared to 38% of standard testers [230]. A descriptive study of rapid testing in multiple venues in the United States found that 100% of individuals testing positive with a rapid test at an NSP were notified of their results and went on to receive results of confirmatory tests [231]. No studies were identified which reported acceptability of rapid testing using oral fluid to target injecting drug users in harm reduction services.

Antenatal

Evidence included: 5 Grade IB, 10 Grade III studies

Women attending antenatal care are tested for HIV in order to identify previously undiagnosed infections and prevent the transmission of HIV from mother to child. Pregnant women can also be tested in the perinatal period, for instance in labour and delivery, in order to administer prophylactic antiretroviral therapy to the infant. A meta-analysis of 18 randomised controlled trials found that antiretroviral therapy given to mothers in the antenatal, intrapartum and postpartum periods was effective in reducing transmission [232]. Evidence also suggests that even if transmission is not prevented, there are clear benefits to infected infants whose mother's HIV infection is diagnosed any time before delivery [233]. A review of antenatal HIV screening policies in European Union Member States found that 18 of 23 responding countries had a national policy with regard to antenatal HIV testing [156]. The countries which do not have a policy to test pregnant women for HIV are Belgium, Greece, Italy, Hungary, and Slovenia. Implementation of antenatal testing policies varies, with some countries rarely testing pregnant women. A study from Poland reported that despite national recommendations to test all women for HIV at their first

prenatal visit, only 3% of women are tested for HIV; although 81% of women indicated willingness to undergo testing [234].

Two Grade IB studies have found HIV testing as part of antenatal care acceptable to pregnant women: reasons cited by pregnant women accepting an HIV test include concern about risk to the baby, concern about own health, and recommendation from healthcare provider [155,235]. No European countries support a mandatory testing strategy [156]. This is in accordance with the literature which has shown such a strategy to be ethically untenable and undesirable to women seeking antenatal care [236,237]. A number of voluntary testing strategies have been employed to increase testing of pregnant women.

Targeted testing has been used in areas with low prevalence of HIV among the population of pregnant women. The European policy review found that only two of 18 countries (Malta and Denmark) have national policies that support risk-based targeted testing. However, two Grade IB systematic reviews conclude that risk-based testing fails to identify a substantial proportion of HIV-infected pregnant women [238,239]. Two Grade III studies have shown that the greatest barrier to testing using a targeted strategy is failure of healthcare provider to offer the test [240,241]. Surveillance from the UK has shown that women who decline testing are at disproportionately high risk of infection [22,233]. Therefore, strategies to increase the number of women accepting an HIV test are needed.

Testing strategies that offer HIV testing routinely to all pregnant women are commonly employed in Europe. A European review found sixteen of 18 countries universally offer HIV testing to women attending antenatal services [156]. Of these, seven countries (Austria, Finland, Ireland, Latvia, Lithuania, Poland, and Sweden) utilise an 'opt-in' testing strategy, while nine countries (Czech Republic, Estonia, France, Germany, the Netherlands, Portugal, Slovakia, Spain, UK) utilise an 'opt-out' testing strategy [60,156,157].

One Grade IB study and one Grade III study have evaluated uptake of testing under an 'opt-in' approach. One randomised controlled study from the UK compared 'opt-in' test offer with a control group where an HIV test was not offered but available on request. The study reported a testing uptake of 5.5% of women in the control group, compared to 35% of women offered testing. Predictors of uptake of HIV testing included offer of test, midwife, younger age, and having previously been tested [87]. One multi-site prospective study from the United States found that 86% of women accepted HIV testing in antenatal care under an 'opt-in' approach, and reasons for declining the test included low risk perception and administrative problems such as limited availability of pre-test counsellors [242].

The 'opt-out' strategy has been trialled in antenatal settings in order to increase uptake of testing and reduce any stigma associated with targeted testing strategies. 'Opt-out' testing has found high levels of acceptability among women. Three Grade III large cohort studies found uptake of testing increased after moving from an 'opt-in' to an 'opt-out' testing approach. One prospective study compared 'opt-out' testing to results from an earlier randomised controlled trial of 'opt-in' testing (discussed in the previous paragraph), and found that testing uptake more than doubled from 35% under 'opt-in' to 88% under an 'opt-out' testing approach [243]. One Canadian study compared HIV testing uptake before and after a clinic policy change from 'opt-in' to 'opt-out' testing and found an increase from 85% to 93% uptake of testing [164]. A similar study from eight antenatal clinics in a southern county in the United States showed an increase from 75% to 88% uptake of HIV testing [158].

The offer of rapid testing in antenatal and perinatal services may improve the effectiveness of HIV testing by facilitating earlier access to antiretroviral therapy to prevent mother-to-child transmission, particularly in labour and delivery settings. A Grade III observational study of rapid testing in pregnant women found that acceptability of the rapid test was overall high (84%) [187]. A Grade III study from the UK showed that rapid and standard HIV testing were equally acceptable to pregnant women (85% and 90%) [94]. In the same study, a survey of women's attitudes towards the rapid test and standard test found that a third of women who declined the standard HIV test indicated they would have accepted a rapid test [94]. Acceptability among midwives was high: 93% of midwives agreed that rapid testing has a role on the delivery ward to identify women who would otherwise decline testing and women who did not engage with healthcare services before delivery [94].

A risk associated with rapid testing is a relatively high probability of false positive results resulting in unnecessary exposure to antiretrovirals. A Grade III observational study in the United States of pregnant women in labour found 4 of 4849 (0.1%) women had a false-positive rapid test result and briefly received antiretroviral prophylaxis before negative confirmatory results [187]. To reduce false-positive results and avoid unnecessary exposure to antiretrovirals, use of two rapid tests during labour and delivery may be used. A Grade IB systematic review found a two-step testing strategy, particularly parallel testing, to be superior to single-test strategy in labour and delivery settings [244].

Brief, rather than in-depth, pre-test counselling has been trialled in the antenatal setting. A Grade IB randomised controlled trial from the United States compared abbreviated pre-test counselling to standard and found that uptake of testing was very high and not significantly different between groups (99% in the abbreviated arm and 97% in the standard arm). Women in the abbreviated arm had significantly lower mean HIV knowledge scores immediately after counselling (78%) compared to women in the standard arm (84%), however knowledge was reassuringly high in both groups [155]. A Grade III prospective study from the UK found that testing uptake was significantly higher when the pre-test discussion was brief [245]. The value of this strategy appears to lie in

reducing the workload and training needs of healthcare providers, and further investigation is warranted especially in places where HIV testing offer and uptake is low in antenatal services.

Termination of pregnancy services

Evidence included: 3 Grade III studies

Few studies on HIV testing in termination of pregnancy services have been conducted. One study of unlinked anonymous testing from Canada found a seroprevalence rate of 0.001% among women seeking termination of pregnancy [246]. However a study from the UK found high reported levels of sexual risk behaviour (40% disclosed one or more risk factors) and low knowledge about HIV transmission (25% correctly identified ways of reducing the risk of mother-to-child HIV transmission) [247]. Anonymous seroprevalence data from women attending one large termination of pregnancy clinic in the UK found an HIV seroprevalence of 1.2%, two times higher than that found in antenatal clinic attendees [248]. As a result in 2008 the UK issued national testing guidelines which recommended the routine 'opt-out' testing in termination of pregnancy clinics. Since this policy change, three Grade III studies of testing in termination of pregnancy services have been published with varying outcomes. All three were conducted in London and offered 'opt-out' testing, excluding known HIV-positive women. The first study found an uptake of 49% with a seroprevalence of 0.6%, which was three times higher than that found in the antenatal clinic [249]. The second study reported uptake of 83% with a seroprevalence of 0.6%, slightly higher than in the local antenatal clinic (0.5%) where one new diagnosis of HIV was made and all women received their results [250]. The third study reporting testing uptake of 37% with standard testing and 41% with rapid testing, and a seroprevalence of 0.5% [251].

Acute care settings

Evidence included: 5 Grade IB, 19 Grade III studies

Acute care settings, including emergency department and medical admissions, represent an opportunity to diagnose HIV infection in ill individuals, particularly in areas with high HIV prevalence. In some countries individuals who experience financial or legal barriers to primary care, such as migrants, may utilise acute care settings as a point of entry into the healthcare system. A systematic review of HIV seroprevalence rates among emergency department attendees in the U.S. found prevalence of 2% to 17% [252].

Acute care settings are often busy and fast-paced environments and HIV testing is often perceived to be impractical due to pre- and post- test counselling requirements, as well as difficulties in ensuring access to care [134,253]. Consequently, acute care settings traditionally provide referrals to individuals identified as high risk to have an HIV test elsewhere. Two Grade III studies looking at uptake of testing among individuals referred from emergency departments have found this strategy ineffective because of poor patient compliance. One prospective study from the United States found only 11% of referred emergency department patients turned up to the referral site for an HIV test [254]. Furthermore, this strategy relies on healthcare providers correctly identifying risk factors for HIV. A survey of healthcare providers in ten emergency departments in the United States found only 45% of high-risk individuals were referred to HIV testing sites or offered a test [253].

These data have led to extensive research into methods to feasibly implement HIV testing in acute care settings, with a focus on streamlining pre-test counselling and use of rapid testing. The bulk of this research comes from the United States in response to 2001 CDC recommendations to expand HIV testing in this setting.

A Grade III study from the UK was the sole European study of HIV testing in acute care setting identified by this review. This prospective study offered HIV testing under an 'opt-in' approach in an emergency department and an acute care unit. Oral fluid non-rapid testing was offered in the emergency department, and standard HIV testing was offered in the acute care unit. Results from this study showed high acceptability of HIV testing, with 61% of emergency department and 70% of acute admissions unit attendees accepting an HIV test. The study reported a prevalence of newly diagnosed HIV infection of 1.0% in the acute care unit and 0.2% in the emergency department. All newly diagnosed patients were successfully transferred into the care of the local HIV specialist clinic [255]. Pre-study focus groups in staff highlighted concerns around the feasibility and acceptability of offering HIV testing to individuals in this setting, particularly with regard to patients asking difficult questions and HIV testing taking too much time. However, post-study focus groups in the same staff take three months after implementation of the testing programme showed far lower levels of concern [138].

Targeted testing has been trialled in one large Grade III study in a United States emergency department in a low-prevalence area offered standard HIV testing to high-risk individuals. Although two thirds accepted an HIV test, the one to two week wait for results meant only 75% of individuals received their results [256].

Five Grade III studies from the United States have compared 'opt-out' testing with targeted testing in the emergency department. Two studies identified more new HIV diagnoses through targeted testing (3% and 11%) compared to 'opt-out' testing (0.7% - 1.2%) [162;163], however the HIV-positive patients identified through targeted testing settings had a lower CD4 count than those identified through 'opt-out' testing, suggesting that 'opt-out' testing identifies HIV infections earlier [162,163]. Moreover, an estimated half of HIV infections remain undiagnosed through targeted testing in this setting, through either having no apparent risk factors for HIV or not

disclosing risk factors to healthcare providers [163]. While targeted testing provides a high yield of HIV diagnoses, it is not an effective strategy for early diagnosis of HIV infection and results in delayed diagnosis of individuals who do not have, or are unwilling to disclose, risk factors for HIV [163,257,258]. An 'opt-in' strategy for HIV testing has found limited success. In a study to measure acceptance of 'opt-in' HIV testing, only 32% accepted the test [259].

As a result, in 2001 the CDC recommended 'opt-out' testing in acute care settings in an effort to increase the number of individuals screened for HIV. One Grade IB review and two Grade III studies from the United States have monitored the impact of this policy change on testing practices [215]. While patient acceptance of HIV testing through an 'opt-out' approach is high [190], no measurable increase in HIV testing rates in emergency departments was found by a nationwide cross-sectional survey in the four years after the CDC recommendations were issued [260]. These data suggest that barriers on behalf of the test providers, including financial and staffing constraints, remain obstacles to implementing such recommendations in acute care settings.

Streamlining the pre- and post-test counselling process has been investigated as a method to make HIV testing less time-consuming in a busy acute care setting. Research into streamlining the pre- and post-test counselling in acute care settings includes:

- One Grade III study has trialled written materials in place of pre-test counselling. The educational materials were made available in a number of languages and were available to patients before and after testing. This strategy was associated with increased feasibility of HIV test offer, but has not been evaluated in comparison with standard pre-test counselling [256].
- Innovative use of video technology to provide pre- and post- test counselling has been reported by three Grade IB studies. Two randomised controlled trials found pre-test counselling by video to be acceptable to emergency department attendees and found knowledge after watching a pre-test counselling video to be comparable to standard pre-test counselling [167,168]. A non-inferiority trial in the United States found that video counselling was an acceptable substitute to pre-test information delivered by an HIV test counsellor [168]. Likewise, a randomised controlled trial in which individuals were assigned to either a standard post-test counselling session or a 15-minute video prior to receiving results found similar post-intervention knowledge scores between both groups [174].

One Grade IB and eight Grade III studies have evaluated the use of rapid testing in acute care settings, all from the United States. Rapid testing has proven successful by removing the need for venipuncture and a second visit to receive their results. Uptake of rapid testing under an 'opt-in' approach has been reported by two prospective studies as 29% to 39% [211,259]. A much higher uptake of rapid testing in conjunction with an 'opt-out' approach has been reported by three prospective studies as between 58% and 95% [163,165,166]. A randomised controlled trial of rapid testing versus standard testing in hospital inpatients and outpatients reported overall acceptance rates of rapid and standard testing of 60% and 41%, respectively. The study also reported that 95% of those receiving the rapid test and 43% of those receiving the standard test were informed of their status [188]. A retrospective study of quality of care of HIV-positive emergency department attendees diagnosed through either rapid testing or standard testing, found those diagnosed through rapid testing were more likely to receive their HIV-positive result compared to standard testers (100% versus 84%). Furthermore, the average time to attend first appointment for HIV care was 22 days after diagnosis among rapid testers, compared to 50 days for individuals diagnosed by standard HIV test [261]. Two prospective studies of rapid testing in an emergency department in the United States found the rapid test process was logistically feasible and patients preferred rapid testing due to the short turn-around time for results [211,262]. Furthermore, a qualitative study has found that healthcare providers in acute care settings report that rapid HIV testing did not interfere with their ability to provide care [263].

Linkage to care of HIV-positive patients diagnosed in acute care settings has been evaluated by several studies. Three Grade III studies of rapid testing in emergency departments in the United States found 79% to 91% of newly diagnosed patients attended their first HIV appointment [264]. A Grade III review of rapid testing in the emergency department found that in most established HIV testing programmes, linkage to care was accomplished by combining the efforts of an HIV counsellor who facilitates patient follow-up with dedicated appointment slots at the nearest HIV clinic [215]. However, the need for provision of a dedicated HIV counsellor is precisely the barrier to testing identified by other studies.

Primary care settings

Evidence included: 4 Grade III studies

Primary care settings represent an opportunity to diagnosed HIV at point of entry to the healthcare system for the many individuals who access primary care more frequently or before other healthcare services [265]. A significant proportion, between a third and three-quarters of HIV-positive individuals have been shown to have attended primary care in the year before diagnosis [71,84]. In countries such as the Netherlands where the healthcare system is mainly operated through GPs, individuals with STI-related symptoms are three times more likely to visit their GP than an STI clinic for such complaints [266]. However, access to HIV testing through primary care is variable across Europe. In one European HIV policy survey, 17 of 24 (71%) responding countries indicated that HIV testing is available through general practitioners [157]. A handful of European countries have a testing

strategy that primarily operates through GPs (Denmark, Germany, the Netherlands, Norway, Spain, and Switzerland) while testing is also offered in other settings, while in other countries GPs remain marginally involved in testing services. In Bulgaria, Greece, Italy, Portugal, and Slovakia, GPs are not involved in HIV testing.

Despite the relative commonness of GP participation in HIV testing, there are few studies evaluating HIV testing in the primary care setting in Europe and developed countries. Early data is emerging from the UK, after testing guidelines in 2008 recommended HIV testing of all adults registering in general practice in areas where diagnosed HIV prevalence in the local population exceeds two in 1000 population [128].

Following this, four Grade III studies of HIV testing in general practice have been published, all from the UK. One prospective study offered rapid HIV testing to individuals registering to general practice in London and found nearly half of eligible participants (45%) accepted a rapid test, with black African and black Caribbean individuals more likely to accept a test compared to individuals from other ethnic backgrounds. Participants felt that having rapid HIV testing available in general practice was acceptable when offered as 'part of a check up', but expressed concerns about the availability of immediate psychosocial support for those testing positive in primary care [267]. A retrospective study of rapid testing in a general practice in a high-HIV-prevalence area of London compared testing characteristics in general practice to that of an STI clinic, and found that general practice rapid testing service was more likely to test and diagnose HIV infection in individuals of black ethnicity compared with the STI setting, which tested more MSM [268]. A similar study from a general practice in a high-HIV-prevalence northern UK city found that while 88% of individuals agreed it is a good idea to offer HIV testing in general practice, only 31% accepted a standard HIV test. The main reason for declining testing was low risk perception. Of interest, of the 123 individuals who consented to testing, only 71 tests were performed, highlighting the difficulties of providing HIV testing in a busy primary care setting [269].

One study evaluated a strategy to increase offer of HIV testing by general practitioners through a training and incentivisation scheme in one high-HIV-prevalence London borough. The scheme resulted in a 300% increase in HIV testing in general practice between over two years, with an increase from 11% to 20% of all new diagnoses in the borough being diagnosed in general practice. Interestingly, the median CD4 count in these diagnoses rose from 280 cells/mm^3 to 351 cells/mm^3, suggesting that increasing testing in general practice resulted in earlier diagnosis of HIV infection [270].

Healthcare services for indicator diseases

Evidence included: 5 Grade III studies

Healthcare services that provide specialised care for diseases that are classified as HIV indicator diseases, such as tuberculosis, lymphoma, and hepatitis B and C, serve populations with a high HIV prevalence. Diagnosis of HIV in patients with co-morbidities that results in initiation of antiretroviral therapy may improve response to treatment and survival [271]. The European AIDS Clinical Society has developed a list of indicator diseases that are associated with a higher than 1% incidence of co-morbid HIV infection, ranging from 3% among individuals with perinatal listeriosis to 94% with meningitis cryptococcosis [272]. Prevalence of HIV among tuberculosis patients is high, with studies in Italy and the UK reporting 10% to 13% of tuberculosis patients with HIV co-infection [273,274]. However, testing interventions must be sensitive to the special needs of this patient group, taking into consideration stress related to the initial diagnosis or fear of added stigma. Healthcare provider barriers also exist, with clinicians from non-HIV specialties sometimes reluctant to get involved in HIV testing [96].

A review of European countries testing policies showed that 13 of 18 (68%) countries report an 'opt-in' approach to testing tuberculosis patients [157]. In the UK, testing is also recommended for patients in healthcare services for those diagnosed with hepatitis B, hepatitis C and lymphoma.

Despite these recommendations, HIV testing rates in indicator disease services is low. Three Grade III studies of test offer in countries that recommend 'opt-in' testing have found wide variation in testing practices between healthcare providers, with many practicing a broader version of risk-based testing. A retrospective study of 'opt-in' testing in a lymphoma clinic in the UK found 41% of patients had not been offered an HIV test by their doctors. Of the patients who were tested, the study found a prevalence of previously undiagnosed HIV infection of 3.5% [275]. In one Australian study, only 43% of respiratory specialists and 80% of infectious diseases specialists responding to an anonymous questionnaire reported offering HIV testing to all tuberculosis patients [96]. A retrospective study from county medical records in the United States found that 63% of tuberculosis patients had been tested for HIV under an 'opt-in' testing strategy, however analysis revealed that HIV testing was largely limited to patients with additional HIV risk factors despite the cohort having an HIV seroprevalence of at least 12% [276].

An 'opt-out' strategy to increase HIV testing has been trialled with mixed results, as reported by two Grade III studies. One study of hepatitis B and C and tuberculosis patients from the UK found an overall decrease in testing from 31% under an 'opt-in' strategy to 20% under an 'opt-out' strategy. Offer of test varied by disease, with 39% of hepatitis B or C patients and 5.5% of tuberculosis patients tested for HIV according to recommendations [277]. In contrast, a retrospective study from Canada reported an increase of HIV testing of tuberculosis patients from 45% under 'opt-in' testing to 82% after 'opt-out' testing was implemented [278].

Community settings

Evidence included: 2 Grade IB studies, 1 Grade IIB study, 11 Grade III studies

The community represents an opportunity for diagnosing individuals who may not have contact with healthcare services, especially in hard-to-reach populations. Community HIV testing facilities provide HIV testing within the community but are not based in hospitals or STI clinics. HIV testing may take place in two different types of community settings: those which are specialist clinics providing sexual health services, such as young people's services or mobile clinics, and those which are non-medical settings, such as bars and sex-on-premises venues.

A Grade IB systematic literature review of 41 community testing studies (including nine studies in the UK, two from the Netherlands, and one from Italy) determined the feasibility, acceptability and effectiveness of carrying out HIV testing in community settings [279]. Thirty-four studies targeted one or more specific populations, including MSM, migrants, IDUs and young people. Uptake of HIV testing ranged from 9% to 75%, and increased uptake was not correlated with any particular population or type of testing facility. Of 24 studies reporting seropositivity rates, 19 found a positivity of 1% or above, with highest rates in venues targeting MSM (2%–6%) and black Africans (3%). A further two studies targeting general population found seropositivity rates of 0.8% and 0.9% [279].

The benefits of rapid testing are most evident in community testing sites, with less access to laboratories and difficulties ensuring return for results at a second visit. One Grade IB, one Grade IIB, and two Grade III studies comparing rapid testing with standard HIV testing reported a significantly higher receipt of results and return for confirmatory testing among rapid testers [229,230,280,281]. Six Grade III studies report attitudes towards, and acceptability of, rapid testing in community settings. All studies found client satisfaction was overall high, and the availability of same-day testing and results does influence the decision to test [181,281–285].

The community presents a special set of challenges to implementing effective HIV testing programmes. Two Grade III qualitative studies in the UK identified patient concerns about community testing, including issues of confidentiality, stigma and whether HIV testing was too serious to be carried out in social settings such as bars [82,286]. One study reported the perspective of the owners of gay venues used for community testing and found that while they were generally supportive of HIV testing, they were also concerns that HIV testing might repel customers, and also that the behaviour of clients would be modified immediately after the test, increasing the possibility of unsafe sex. There are also some reservations about the safety of HIV testing in non-medical settings [286]. One Grade III United States study reported the main difficulties faced by services providing community testing included staffing, training, contacting patients for positive results and sustainability of programmes [287].

Prisons

Evidence included: 2 Grade IIA, 3 Grade III studies

Prisons are controlled environments in which HIV testing may be offered to a high-risk population that may be otherwise hard to reach. A cross-sectional survey of HIV infection and related risk behaviour in six European male prison populations in France, Germany, Italy, the Netherlands, Scotland, and Sweden found that prisoners reported high levels of HIV risk behaviour including: 25% ever injecting drugs, 71% had unprotected sexual intercourse with last casual partner, 3% reported sex with a man in the previous year, and 18% reported ever tattooing in prison, two thirds of whom had used shared needles. The survey offered anonymous HIV testing and found HIV seroprevalences ranging from 0.7% to 4.4% in the male incarcerated population [288]. A review of European HIV testing policies showed that 11 of 18 (61%) of European Union countries surveyed have policies to routinely test prisoners [157]. Despite these policies, there is little data on HIV testing rates and testing strategies in European prisons.

One large Grade III observational study from 48 correctional facilities in the United State reported the uptake and seroprevalence rates from HIV testing programmes in prisons using an 'opt-in' testing strategy. The study reported that testing uptake tripled between 1992 and 1998, and found an HIV prevalence of 3.4% in the incarcerated populations, with most new infections identified in prisoners whose identified risk was heterosexual contact (44%) followed by injecting drug use (37%) [289].

In prisons, use of rapid testing may be preferable where prisoners may be released early. Two Grade IIA prospective controlled studies from the United States of an 'opt-out' testing strategy using rapid oral mouth swab testing with written consent and without pre-test counselling reported an uptake of 59% in the men's prison, and 78% in the women's prison, with higher rates of uptake among individuals tested within 24 hours of arrival. Receipt of results in both studies was 99% [290,291].

Two Grade III studies from the United States report uptake and receipt of result using a rapid testing strategy. A prospective study of rapid testing in a women's county jail resulted in an uptake of 46%. While 99.7% of women received their results, only 22% of the newly diagnosed prisoners entered into care, and none were retained in care six months after diagnosis [211]. A retrospective study of rapid testing in newly arriving inmates who requested or were referred to testing by medical staff found that 6% of booked inmates were tested for HIV. Of those who tested, 99.9% received their test results. Almost half (46%) of the inmates with a newly diagnosed

infection reported heterosexual contact or no HIV risk behaviours. All individuals with reactive tests were referred to care, although the study did not report rates of entry into care [292].

Youth services

Evidence included: 1 Grade IB study, 6 Grade III studies

Young people are a poorly defined demographic which is underrepresented in the literature. Incidence estimates from the UK suggest that one in six new HIV infections occur in young people aged 16 to 24 years [293]. Ongoing HIV transmission among young people reflects a higher rate of risky sexual behaviour, higher rates of STIs, and multiple partnerships compared to older people [294]. However, testing rates among young people are low in many European countries due to a number of barriers [295]. Two qualitative studies of young people in the United States found that cost, lack of health insurance, and fear of judgement were the main barriers to HIV testing among young people aged 18 to 26 [296,297]. Where free access to HIV testing is not available, financial barriers also exist for young people.

Youth services exist in some European countries to provide personal and social support to young people, often targeting at-risk communities. Established youth services present an opportunity to provide HIV testing to young people who may not present to other healthcare services. Despite growing interest in this area, there is little data evaluating HIV testing interventions in youth services. One Grade III qualitative study evaluated experiences of young people aged 18 to 24 who accepted an HIV test in youth services in Sweden and found that young people prefer a quick and easy testing procedure including a short pre-test discussion and telephone receipt of the test result [298].

A wider body of evidence is available on HIV testing interventions specifically targeting young people in medical or community settings. Three Grade III studies of standard HIV counselling and testing in young people were identified. In the UK, a pilot of HIV testing within a community organisation providing sexual health advice to young people reported 72% of men aged 16 to 25 years accepted standard HIV testing and counselling [299]. Acceptance of HIV testing among young people (aged 13 to 22) attending family planning clinics in the United States was lower in another study, with 46% agreeing to HIV testing [300]. HIV testing may be more acceptable to young people compared to older people, as one study from an emergency department in the United States reported 61% of young people aged 15 to 21 accepted HIV testing compared to 45% of adults aged 21 to 54 [294]. These three studies all offered standard HIV testing and counselling and found previously undiagnosed seropositivity rates ranging from 0.0% to 0.4% [294,299,300].

Strategies such as alternative test result notification and rapid testing have been trialled in one Grade IB and two Grade III studies to increase the number of young people receiving their test results as studies have reported that only 33% and 86% young people testing with standard HIV testing and counselling return to receive their results [299,301–303]. One randomised controlled trial from the United States compared two methods of giving HIV test results to young people (aged 13 to 24) at community testing sites, and found that 37% of those assigned to face-to-face notification returned to receive results compared with 58% of those assigned to telephone notification receiving their results [302]. One United States study comparing preference of rapid testing to standard testing in an urban hospital-based adolescent primary care clinic found 70% of individuals aged 13 to 22 chose rapid testing over standard testing, and those who chose a rapid test were more likely to receive their test results (91% vs. 47%) [304]. This study also found that young people preferred oral fluid rapid testing over other forms of rapid testing requiring venipuncture or finger prick [304]. This was supported by another study from the United States which evaluated youths' (aged 13 to 24) preference for six different HIV testing methods: one oral fluid rapid test, two oral fluid non-rapid tests, one urine non-rapid test, and two finger-prick rapid tests). The study found the oral fluid rapid test was preferred because it was less invasive and because it provided quick results [305].

Anonymous testing

Evidence included: 2 Grade III studies

Anonymous testing services offer HIV testing without requiring name or other personal identifier. Some rely on this type of delivery of HIV testing where there may be fear of stigma and discrimination, or where financial and legal barriers to HIV testing exist. One review of European HIV testing practices found anonymous testing available in all European Union countries except the UK [157]. Anonymous testing can be provided in healthcare settings, such as STI clinics, or in community and non-healthcare settings, such as prisons. In France, 15% of all HIV tests are anonymous, coming from 339 anonymous HIV testing centres including 105 in prisons, and 170 centres affiliated to hospitals [306].

There is evidence that individuals choosing anonymous testing have a higher burden of HIV than those choosing confidential HIV testing [307]. In at least eight European countries (Austria, Czech Republic, Estonia, Germany, Hungary, Poland, Slovakia, and Slovenia), disenfranchised populations such as uninsured individuals, non-residents or undocumented migrants can access testing free of charge only through anonymous testing facilities [157]. Furthermore, populations with higher risk behaviours, such as injecting drug users and MSM, often opt for

anonymous testing [307]. Anonymous testing is usually free of charge, although in Germany a fee applies which may be waived under certain circumstances [157].

Rapid testing has found extremely high acceptability in anonymous testing sites, with two Grade III studies from the United States and Canada reporting between 91% and 96% of attendees choosing a rapid test over standard testing [281,308]. Rapid testing has also resulted in a higher proportion receiving test results, with 100% of those opting for rapid testing receiving results, compared with 86% to 91% of those choosing standard testing [281,308]. An important disadvantage of anonymous testing is that it is difficult to ensure access to care for those diagnosed with HIV infection. No studies were found on strategies to ensure access to care.

4 Conclusions

Surveillance data from a number of European countries over the past decade reveal high and increasing numbers of undiagnosed infections and a high proportion of late presenters among those diagnosed. These findings indicate that current efforts to diagnose HIV early are failing and there is an urgent need to review current HIV testing strategies across Europe. The aim of the review was to review the available literature on the benefits of testing for HIV, barriers to testing and effective strategies to overcome these while ensuring access to treatment and care.

The individual benefits of HIV testing are undisputed. Without it, infected individuals will remain unaware of their infections for many years and eventually present with an AIDS-related illness, which, left untreated, will lead to a fatal outcome. In contrast, early diagnosis and treatment of HIV infection today guarantees an almost normal life span largely free of serious illnesses. There is also important new research suggesting the public health benefits of HIV testing, both in terms of promoting safer sexual behaviour among diagnosed individuals and reduced infectiousness related to antiretroviral treatment.

The cost of treatment and care for individuals diagnosed promptly after infection is significantly lower than for those diagnosed late in the course of infection. In the United States and France, routine one-time testing was found to be cost effective, even in low HIV prevalence populations. Cost effectiveness is improved when secondary transmission benefits are included, and when newly diagnosed patients are successfully linked to HIV treatment and care.

Barriers to HIV testing are well described in Europe, with three reviews drawing from nearly thirty European studies which identified various barriers to testing, most of which were published in the past five years. The majority of studies focus on the needs of sub-Saharan African and MSM populations. For ease of reference, identified barriers were categorised at the individual, healthcare provider and institutional levels. These included:

- Individual level barriers: low risk perception, low knowledge of HIV and benefits of treatment, lack of information about how and where to access testing as well information around the test itself, stigma and concerns regarding confidentiality.
- Healthcare provider barriers: lack of training to perform HIV testing and counselling, low knowledge levels about HIV resulting in poor risk assessment, and discomfort approaching the subject of HIV and sexual histories of patients.
- Institutional barriers: lack of or poorly implemented HIV testing policies and programmes, lack of allocated resources, the presence of legal and financial obstacles in accessing care, for example among undocumented migrants and IDUs.

The review found a number of strategies to overcome these barriers. Mass media HIV campaigns were shown to have an impact on behaviour, with most HIV testing campaigns successfully increasing HIV testing rates in the short term. There was less evidence of changes in knowledge and attitudes towards HIV following such campaigns.

There was good evidence showing that individuals are more likely to test when they perceive a benefit to diagnosis. While medical benefits were clearly important, these benefits alone did not appear to be sufficient to motivate individuals to test. Addressing concerns of stigma and perceived discrimination was particularly important. These barriers were addressed by 'normalisation' of the testing procedure and the introduction of a universal offer of an HIV test (sometimes referred to 'opt-out' testing). All published literature comparing universal offer ('opt-out') testing with a risk based ('opt-in') found higher uptake rates in setting where testing was offered to all individuals as part of routine care ('universal' offer). This approach was found to be highly acceptable to both patients and staff in a variety of settings. Furthermore, the recommendation of HIV testing from a healthcare provider was important in the patient's decision to test. Training healthcare providers increased HIV testing rates, improved healthcare providers' attitudes towards HIV, and boosted confidence when conducting tests.

It must be noted that the review found inconsistent use in the literature of the terms 'opt-in' and 'opt-out' testing, and these were frequently interchanged or misused. Additionally, there is some redundancy, with terms indiscriminately being interchanged or combined with terms such as 'routine,' 'universal' and 'provider-initiated' testing. The term 'universal offer' of testing best describes a routine offer of an HIV test to all individuals and we would recommend avoiding the terms 'opt-out' , 'opt-in' and provider initiated.

Studies showed that counselling is effective in reducing sexual risk behaviour among HIV-positive individuals and therefore also reducing the risk of onward transmission of the infection. However, limited or no benefits were identified in those who tested HIV negative. These findings cast some doubts on the effectiveness of pre-test counselling. Historically, prior to antiviral therapy, pre-test counselling was a fundamental part of the HIV testing process. It provided a valuable opportunity to discuss an individual's risk of HIV and given that no effective treatment was available, many patients chose not to test. In the era of effective antiretroviral therapy, the benefits of testing and treatment far outweigh any potential adverse impact related to testing. The literature review also found little evidence that conveying safer sex messages prior to an HIV test reduces sexual risk behaviour. Furthermore, some healthcare providers found pre-test counselling intimidating and time-consuming and a barrier to testing. This was particularly the case in non-traditional settings where HIV testing is increasingly conducted by

non-HIV specialists. Alternatives to pre-test counselling were evaluated. Brief pre-test information was found to be acceptable to patients and effective in with conveying knowledge about HIV and associated risk behaviours. Innovative use of video or other technologies were also effective.

Alternative diagnostic tests to simplify the testing process and motivate both patients and staff have been trialled in recent years. The introduction of rapid tests have been acceptable to both patients and staff, with the additional benefit of increasing receipt of results compared to conventional HIV tests in some studies. These tests are promising in a range of setting including testing in the community.

The literature confirmed that routine offer of HIV testing in antenatal, STI, and harm reduction services is acceptable and effective. However, more studies are needed in non-traditional settings, such as acute and primary care settings and prisons. Of concern was the low proportion of newly diagnosed individuals seeking HIV treatment and care following testing in prison, community, and anonymous testing sites.

The review identified some important gaps in our knowledge. Overall, few high quality studies were conducted in the area of HIV testing in Europe. The United Kingdom is the EU/EFTA country with the largest number of studies in this field, followed by the Netherlands, France, and Italy. While there is no doubt of the benefit of HIV testing and treatment for the individual, further evidence is required to better understand the impact of HIV testing and treatment on reducing transmission at the community level.

Evidence of effectiveness of HIV testing initiatives from Europe are lacking, particularly in non-traditional settings, such as community and acute care settings. More research is also needed to determine the optimal frequency of HIV testing among all populations. There is currently no evidence to support annual or more frequent testing of any population. Current policies on testing frequency are primarily guided by expert opinion. Although all European countries have an HIV testing policy in some form, there is some evidence that HIV testing practice varies. Audits of national HIV testing guidelines are needed to identify problems in implementation and other needs, such as training of healthcare providers or logistical barriers. Finally, only one study on the cost-effectiveness of HIV testing has been conducted in Europe

Much of the evidence in the review has been therefore drawn from studies conducted in the United States. While many findings can be extrapolated to the European context, it must be noted that the HIV epidemic in the United States has unique features and the delivery of healthcare is very different to many of the European countries. For example, the United States has recommended scale up of HIV testing in acute settings such as the emergency departments as a key strategy for identifying infections in vulnerable populations such as black Americans. It may not be the case that vulnerable populations in Europe attend these facilities in large enough numbers to warrant a testing programme in this setting.

Despite these caveats, the evidence from the United States provides valuable evidence on strategies or approaches that are transferable to the European setting. These findings highlight the need to expand testing across Europe to ensure that HIV programmes are vigorously monitored and evaluated. With few randomised controlled trials feasible on HIV testing strategies, high quality outcome evaluation data will be critical in assessing the acceptability, feasibility, effectiveness and cost-effectiveness and sustainability of HIV programmes at the local and national level.

Appendix 1: List of countries

European Union Member States

Austria
Belgium
Bulgaria
Cyprus
Czech Republic
Denmark
Estonia
Finland
France
Germany
Greece
Hungary
Ireland
Italy
Latvia
Lithuania
Luxembourg
Malta
Netherlands
Poland
Portugal
Romania
Slovakia
Slovenia
Spain
Sweden
United Kingdom

EEA/EFTA Member States

Iceland
Switzerland
Norway
Liechtenstein

Appendix 2: Search methods

The following is the search strategy for HIV-testing-related publications with the number of articles identified with each term individually, and in combination.

1	hiv.ti,ab	175683
2	exp HIV/	67268
3	1 or 2	185321
4	(test* OR counsel* OR VCT OR 'voluntary counsel*' OR HIV-ct).ti,ab	1701495
5	exp MASS SCREENING/	81836
6	4 or 5	1759277
7	(austria* OR belgi* OR bulgaria* OR cyprus* OR cypriot OR czech* OR denmark* OR danish* OR estonia* OR finland* OR finnish* OR france* OR french* OR german* OR greec* OR greek* OR hungary* OR hungarian OR iceland* OR ireland* OR irish* OR italy* OR italian OR latvia* OR lithuania* OR luxembourg* OR malta* OR maltese* OR netherland* OR holland* OR dutch* OR poland* OR polish* OR portug* OR romania* OR slovak* OR sloven* OR spain* OR spanish* OR sweden* OR swedish* OR switzerland* OR swiss* OR liechtenstein* OR norway* OR norweg*).ti,ab	453337
8	exp GREAT BRITAIN/	255011
9	exp EUROPE/	921646
10	europe*.ti,ab	122226
11	('united kingdom' OR UK OR scotland OR scottish OR england OR english OR wales OR welch OR london OR britain OR british).ti,ab	179173
12	(madrid* OR milan* OR barcelona* OR berlin* OR paris* OR athens* OR rome* OR katowice* OR hamburg* OR naples* OR warsaw* OR frankfurt* OR munich* OR brussels* OR lisbon* OR vienna* OR manchester* OR brighton* OR budapest* OR amsterdam* OR stuttgart* OR stockholm* OR bucharest* OR rotterdam* OR copenhagen* OR lyon* OR prague* OR zurich* OR dublin* OR helsinki* OR riga* OR sofia* OR talinn* OR reykjavic* OR oslo* OR vilnius* OR bratislava* OR ljunljana*).ti,ab	91528
13	7 OR 8 OR 9 OR 10 OR 11 OR 12	1310908
14	3 AND 6	36916
15	13 and 14 [Limit to: Publication Year 2005-Current and (CheckTags Humans)]	1327
16	exp UNITED STATES/	946882
17	exp CANADA/	98219
18	exp AUSTRALIA/	77293
19	16 or 17 or 18	1104372
20	14 and 19 [Limit to: Publication Year 2005-Current and (CheckTags Humans)]	1593
21	15 OR 20 [Limit to: Publication Year 2005-Current and (CheckTags Humans) and (CheckTags Humans)]	2829

Appendix 3: Levels and grading of evidence

Table A

Level	Type 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 controlled study without randomisation
IIb	Evidence obtained from at least one 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

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