



ECDC **GUIDANCE**

HIV testing: increasing uptake and effectiveness in the European Union

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List of abbreviations

AIDS	Acquired immunodeficiency syndrome
ART	Antiretroviral therapy
EACS	European AIDS Clinical Society
ECDC	European Centre for Disease Prevention and Control
EEA	European Economic Area
EFTA	European Free Trade Association
EIA	Enzyme immunoassay
EMCDDA	European Monitoring Centre for Drugs and Drug Addiction
EU	European Union
HIV	Human immunodeficiency virus
IDU	Injecting drug user
IUSTI	International Union against Sexually Transmitted Infections
MSM	Men who have sex with men
M&E	Monitoring and evaluation
STI	Sexually transmitted infection(s)
UNAIDS	United Nations Programme on HIV/AIDS
UNODC	United Nations Office on Drugs and Crime
UNGASS	United Nations General Assembly Special Session
UK	United Kingdom
US CDC	United States Centers for Disease Control and Prevention
WHO	World Health Organization

Glossary

Care pathway	A methodology for the mutual decision making and organization of care for a well-defined group of patients during a well-defined period.
Clinical governance	A systematic approach to maintaining and improving the quality of patient care within a health system.
HIV indicator disease/condition	A disease or condition suggestive of underlying HIV infection; not necessarily only found in the presence of HIV.
Incidence	The rate at which new cases of a condition occur in a susceptible population during a specified period; usually expressed as a number per 100 000 in a year.
Indicators	Defined measures which are formed from data collected as part of the monitoring and evaluation.
Informed consent	Consent by a person to undergo a medical or surgical investigation or treatment after the person understands the risks involved in the treatment and/or the consequences of the possible results of the investigation.
Partner notification/partner referral	A formal and systematic means of identifying the sexual partner(s) of an index patient diagnosed with a sexually transmitted infection and informing them of the need for diagnosis and treatment of a possible infection.
Post-test counselling	Discussion following a test result designed to provide advice on how to proceed in light of the result.
Pre-test discussion	Short focussed discussion explaining the benefits of testing and how results are given for the purpose of obtaining informed consent to the test.
Pre-test information	Sometimes used to mean the same as pre-test discussion, but also describing written information explaining the benefits of testing and how results are given (informed consent is then obtained verbally).
Pre-test counselling	Longer intervention including a sexual history and risk assessment designed to perform the same functions as pre-test discussion, but also to establish the person's likely response to the possible result.
Psychosocial care/psychosocial support	A non-therapeutic intervention that helps a person cope with stressors at home or at work.
Prevalence	The proportion of a population that are cases with a certain condition at a specific point in time.
Reactive result	Result of a screening test initially indicating HIV infection requiring confirmation using a diagnostic test.
Referral pathway	A series of steps designed to ensure referral of patients to appropriate services. It is developed by establishing relationships between sexual health services and relevant healthcare agencies and involves a shared understanding and agreed ways of working together to better address the sexual health needs of a defined population.
Routine offer of HIV testing	Everyone attending a service, or presenting with a given condition, is offered or recommended an HIV test with pre-test discussion but without the need for a risk assessment.
Seroprevalence	The proportion of a population at a specific point of time that test positive for antibodies to an antigen based on serology.
Sexual and reproductive health services	Health services that provide family planning, prevention of unsafe abortion, management of reproductive tract infections and sexually transmitted infections, including HIV, and promotion of sexual health.
Surveillance	The continued watchfulness over the distribution and trends in the incidence of disease through the systematic collection, consolidation and evaluation of morbidity and mortality reports and other relevant data.
Universal offer/recommendation of an HIV test	Everyone attending a service is offered or recommended an HIV test with pre-test discussion but without the need for a risk assessment.

1 Introduction

The number of people infected with HIV continues to rise across Europe, with the epidemic largely concentrated in certain sub-populations, including men who have sex with men, migrants (especially those from countries with high HIV prevalence) and injecting drug users. Levels of undiagnosed HIV infections are still high. Many people with HIV remain undiagnosed until late in the course of infection and so cannot benefit from earlier treatment that reduces morbidity and mortality. It is also recognised that persons diagnosed early are less likely to transmit the virus because of lower infectivity and changes in risk behaviour. Thus HIV testing, early diagnosis and treatment may have both individual and public health benefits.

In essence a set of laws, guidelines and recommendations applying to HIV testing is in place in all European countries. The contents of the regulations range from specific rules targeting HIV testing to wider rules linked to quality of care and good medical practice.

Countries in Europe report high levels of antiretroviral treatment coverage for those known to be HIV positive. The issue is the extent to which people living with HIV who need treatment are unaware of their infection. Reported rates of HIV testing among intravenous drug users vary considerably across European countries – from less than 1 % to 84 %. Among men having sex with men, reported rates vary from less than 1 % to almost 70 %. Data from selected countries have shown rates of late diagnosis from 26 % to 53 %. More than half of those patients where a CD4 count was performed at the time of diagnosis had a CD4 count of less than 350 cells/mm³ [1].

There is a need for action. Low-risk perception is an important barrier to being tested. Patients must be aware of their risk and their need to be tested. On the patient side, barriers to actually seek HIV testing are mainly related to fear – fear of a serious diagnosis, stigma and discrimination; on the provider side, a main barrier to offering HIV testing is reluctance to touch sensitive topics which education and training could overcome. Regarding the testing procedure laws, policies and guidelines play a crucial role as they prescribe requirements to support the testing procedure, such as confidentiality, counselling, informed consent, partner notification and referral of the HIV-diagnosed patients to medical and psychosocial care.

1.1 Scope and purpose of this guidance

This evidence-based guidance is designed to inform the development, monitoring and evaluation of national HIV testing strategies or programmes in the countries of the European Union (EU) and the European Economic Area (EEA).

It is intended to complement the following existing guidance:

- Scaling up HIV testing and counselling in the WHO European Region as an essential component of efforts to achieve universal access to HIV prevention, treatment, care and support. Policy framework [2]
- European Guideline on HIV Testing [3]
- Guidance on provider-initiated HIV testing and counselling in health facilities [4]
- Guidance on testing and counselling for HIV in settings attended by people who inject drugs. Improving access to treatment, care and prevention [5]

The evidence base to support this guidance has been provided by the findings and conclusions of a systematic literature search and evidence synthesis presented in the accompanying document *HIV testing: Increasing uptake and effectiveness in the European Union. Evidence synthesis for Guidance on HIV testing* [6]. The points in this guidance are referenced, but for a fuller explanation of the rationale for the recommendations, readers are directed to the evidence synthesis.

1.2 Why is it important to test for HIV?

Across Europe the number of people infected with HIV continues to rise, and the problem of late diagnosis has been described in many countries.

At the end of 2008 there were an estimated 850 000 people with HIV in western and central Europe [7]. The survival of many is due to advances in the treatment of HIV infection which have dramatically improved the health and life expectancy of those infected. However, the number of people becoming infected each year continues to rise, with 25 656 newly diagnosed cases of HIV infection reported by the countries of the EU and EEA in 2008 [7].

The European HIV epidemic is largely concentrated in certain sub-populations, including men who have sex with men, migrants (especially those from countries with high HIV prevalence) and injecting drug users, although the

prevalence of HIV among these groups and others may vary considerably within and between countries [7]. (See further, Section 2.1).

There are still high levels of undiagnosed HIV in Europe. It has been estimated that in EU Member States 30 per cent of those infected are unaware of their infection [8].

There is strong evidence that earlier treatment reduces morbidity and mortality, but many people with HIV remain undiagnosed until late in the course of infection.

The problem of late presentation at HIV diagnosis has been described in many countries throughout the world, but definitions of late diagnosis vary considerably. Estimates within Europe range from 12 per cent to 61 per cent of infections diagnosed late, depending on whether this was defined by CD4 count at presentation, presentation with AIDS at diagnosis or progression to AIDS within varying timeframes following diagnosis [9–11].

A late diagnosis of HIV infection (i.e. when the CD4 count is less than 350 cells/mm³ and antiretroviral therapy should therefore have started in line with current clinical guidelines [12], or a patient presents with AIDS [13]) results in a very much higher probability of morbidity and mortality [14,15]. Thus, early diagnosis of HIV infection can benefit the individual, with appropriate initiation of treatment leading to a much improved prognosis [16–20]. It is also more cost-effective in both the short [21] and long term with fewer episodes of acute serious illness [22].

As HIV infection may have almost no symptoms for many years, testing is the only way to achieve early diagnosis, enabling early referral for treatment and care.

People diagnosed early may also be less likely to transmit the virus to others because of both lower infectivity when treated and changes in sexual and drug injecting behaviour. Mother-to-child transmission can be effectively prevented by HIV testing and treatment of pregnant women.

It is now well recognised that antiretroviral therapy reduces an individual's infectivity by lowering concentrations of virus in genital secretions to levels below those at which transmission is likely to occur [23].

Mother-to-child transmission is drastically reduced by initiating antiretroviral therapy for pregnant women who are diagnosed with HIV before or during pregnancy, and consequently many European countries include routine HIV testing in antenatal screening programmes [24,25].

There is also evidence that people diagnosed with HIV take great care not to transmit the infection. HIV-positive individuals have been found to have more consistent condom use than those who are HIV-negative, and decreased levels of unprotected sex have been reported following an HIV diagnosis [26]. HIV-infected men who have sex with men have reported significantly lower rates of unprotected sex with partners of different or unknown HIV status than with partners of the same status [27], and an HIV diagnosis during the period of primary infection has been shown to motivate the majority of men to reduce their risky behaviours substantially [28].

Early diagnosis of HIV thus has great benefits for both the individual and the community. Increasing the proportion of people with HIV who receive an early diagnosis is a critical public health priority.

1.3 Core principles for national HIV testing strategies and programmes

It is recognised that the countries of Europe currently vary widely in their political and social approaches to HIV but to ensure that a national HIV testing strategy takes an ethical approach based on human rights, countries need to adhere to the following principles. As far as possible, these principles are based on evidence, but in some cases they are aspirational and have their basis in accepted best practice and expert consensus.

HIV testing should be voluntary, confidential and undertaken with informed consent

There should be easy access to voluntary testing for everyone and special efforts need to be made to ensure this for groups most at risk for, and vulnerable to, HIV. These will include people who are hidden or marginalised in society for whom access to testing should be encouraged without coercion or breach of confidentiality.

A national HIV testing strategy must primarily serve the needs of those who are infected and as yet undiagnosed. People must be able to choose to test for their own benefit rather than be coerced or compelled, even where this would be deemed to be in the interests of the wider public health. Their decision to test must be based on informed consent.

Confidentiality is a fundamental principle of all healthcare and is of particular importance to HIV testing. Fear of a breach of confidentiality will deter individuals from seeking HIV testing or accepting it when it is offered [29–31].

In Europe, the communities most affected by HIV are socially marginalised and this, combined with HIV-related stigma, can create a barrier to HIV testing [32,33]. Services therefore need to be designed in such a way that members of those communities can come forward without fear of reprisal or blame.

This is best achieved by making HIV testing available in a wide range of settings, both medical and non-medical, delivered by appropriately trained and competent staff. There should be clear referral pathways to, and support from, HIV specialist services.

Ensure access to treatment, care and prevention services

The single biggest benefit of HIV testing is access to treatment. Providing universal access to treatment and care, prevention and support services, with clear referral pathways, must be a cornerstone of national HIV testing strategies.

Treatment is defined as treatment for HIV infection itself, treatment for conditions arising from it and treatment for conditions which place people at risk of HIV infection (e.g. drug dependencies). It should be complemented by access to psychosocial care and support, and prevention services.

This principle should apply to all population groups including undocumented migrants or migrants of uncertain residency status for whom access to healthcare may be limited by existing policies.

Where it does not apply under current structures, consideration should be given to ways of making such treatment accessible, in line with the 2001 UNGASS *Declaration of Commitment on HIV/AIDS* and the 2004 *Dublin Declaration on Partnership to Fight HIV/AIDS in Europe and Central Asia* which commit EU Member States to providing universal access to comprehensive HIV prevention, treatment, care and support programmes by 2010.

Show political commitment

Government priority for the HIV testing programme is required in order to achieve impact. This needs to be supported by financial investment, which should be monitored to ensure that funds are used in a cost-effective way.

Increasing the proportion of people with HIV who receive an early diagnosis is a public health priority. This needs to be reflected in national health strategies, legislative programmes and spending plans. Leadership is needed to motivate and support decision makers at all levels, to provide incentives for widening the reach of voluntary confidential testing programmes and ensuring they are appropriately targeted, and to overcome structural and attitudinal barriers.

Adequate financial resources need to be provided for HIV testing programmes as well as for HIV surveillance, prevention, treatment, care and support services.

Reduce stigma

The stigma that is still attached to HIV is a barrier to testing, especially among communities that are themselves stigmatised and among healthcare workers. 'Normalising' testing, e.g. making the process more like that for other screening and diagnostic tests, can help counter this, although testing must remain voluntary.

HIV and the behaviours most commonly associated with its transmission can be highly stigmatised; this is a significant barrier to HIV testing and can operate on an individual level and on structural or institutional levels such as in the workplace or in healthcare services [32–34].

Public education campaigns have been shown to increase HIV testing rates [35,36] and these increases may in part be the result of decreasing the stigmatisation of HIV. It is important to dispel myths about the ways in which the virus is transmitted, to promote HIV testing as a normal part of healthcare and to emphasise the advances in treatment which mean that HIV infection is no longer a fatal illness but a chronic condition. Visible and high-level support from opinion formers, including politicians, community leaders and celebrities, as well as supportive and accurate coverage in the media, can all be used to raise awareness.

The engagement of healthcare workers is central to any HIV testing strategy. A proactive approach to HIV testing on the part of healthcare workers has a positive influence on the individual's decision to accept the offer of a test [37]. However, HIV-related prejudice among healthcare workers in some countries has been described [38,39] and efforts need to be made to minimise the impact of this on HIV testing rates.

Remove legal and financial barriers

Testing strategies should find ways to overcome legal and financial disincentives to testing. Such barriers may include policies of criminal prosecution for HIV transmission, or the requirement to pay for treatment where this is unaffordable. With the exception of mandatory testing of blood and tissue donations anti-discrimination legislation and policies to prevent mandatory testing for any group in any setting should be considered.

Disincentives to HIV testing may include laws which criminalise sex between men, sex work and use of illicit drugs, as they may require disclosure of illegal acts [40]. In particular, criminal prosecutions for HIV transmission or exposure are unlikely to serve the interests of public health and may create a situation where remaining undiagnosed constitutes a defence for the individual.

The following measures may be considered:

- Changes in law, and/or how existing law is applied, relating to groups at higher risk of HIV to create an environment in which they are able to come forward for testing without fear of reprisal.
- Changes in law to decriminalise homosexual behaviour.
- Anti-discrimination legislation to protect those diagnosed with HIV and minority groups most at risk of HIV.
- Policies or legislation to prevent mandatory testing or testing without consent, for any group in any setting, such as in prisons or for migrants seeking to enter the country [41] (although there are specific situations where HIV testing is necessary to fulfil certain functions such as for blood and organ donors, and in relation to possible professional exposure).

Governments need to ensure that healthcare systems are set up in such a way that no one is denied treatment on grounds of inability to pay for it. This may require rethinking models and conditions of access to healthcare in some countries. Similarly, no one should be denied an HIV test because they cannot afford to pay for it.

Make access to HIV testing an integral part of national strategies

Any national strategies for the prevention and treatment of HIV, other sexually transmitted infections, viral hepatitis, tuberculosis and other HIV indicator diseases must include HIV testing, with appropriate targeting, as a key element. Opportunities to increase access to, and uptake of, voluntary confidential HIV testing should also be identified within other relevant national strategies, such as those targeting pregnant women, drug use, sex work or healthcare in prisons.

The relationship between the presence of sexually transmitted infections (STI) and increased probability of HIV infection is well documented, as is the similarity of transmission routes [42,43]. The IUSTI/WHO Europe 2008 *European Guideline on HIV testing* recommends that all individuals who seek evaluation and treatment in STI clinics should be offered an HIV test [3].

It is now widely accepted that antenatal screening programmes should include universal HIV testing and many European countries have adopted this approach [44]. There have been calls for strategies for the management of individuals with tuberculosis, viral hepatitis and lymphoma to include a routine offer of HIV testing, based on the prevalence of these conditions in people with HIV and on the need to manage them differently in people with HIV co-infection [45,46].

National strategies concerning behaviours or settings which increase the risk of HIV transmission or population groups at higher risk of HIV, such as those on the management of illicit drug use, sex work, or healthcare in prisons, can provide opportunities to increase the reach of effectively targeted HIV testing. Where HIV prevalence in prisons is known or estimated to be high, access to HIV testing for prisoners should be an essential component of HIV testing programmes. Care should be taken to ensure this is always undertaken with informed consent and without coercion or breach of confidentiality, in line with the core principles of this guidance and UNODC/UNAIDS/WHO recommendations [47].

Wherever possible, testing for STI and viral hepatitis should be offered alongside HIV testing for population groups at higher risk.

Develop and implement an HIV testing strategy with the participation of stakeholders

Use available information about HIV and related issues nationally and locally to help clarify what needs to be achieved and where the priorities lie. Encapsulate this in a set of strategic aims and objectives, so that everyone involved or affected has a shared understanding. Developing the strategy requires the participation of all major stakeholders in order to build a coalition around shared objectives. These include people living with HIV, representatives of communities most affected, civil society and prevention agencies, professionals with expertise in HIV testing and others with a role in implementing the strategy.

The implementation and delivery of the strategy will also need to involve all these groups, not only the healthcare professionals. When setting the objectives, identify how progress against them will be monitored.

It is essential to use the best available evidence, knowledge and epidemiological information to help clarify strategic aims and objectives, and to set priorities. Where evidence is lacking, structures need to be put in place to improve it. More information on evidence to support strategy development and monitoring is provided in Sections 2.1 and 3.

2 Developing a national HIV testing strategy

Just as every country in Europe is socially and culturally distinct, so is every country's HIV epidemic. A prerequisite for any successful HIV testing strategy is good quality information. It is important to form as accurate a picture of the epidemic as possible and to identify barriers to, and facilitators for, testing. This information will determine the most important population groups to target and the most suitable sites for HIV testing. This in turn will help to identify the measures that need to be taken to implement the strategy, such as financial resourcing, service reorganisation, staff training and awareness-raising among the target populations.

2.1 Whom to test?

Know your epidemic and identify groups most at risk. An effective national approach to HIV testing will rely on having an understanding of the epidemic at local and national level. Testing programmes should aim to reach those at risk of infection and to prioritise those at highest risk.

Identify and review available surveillance and other relevant data, including information on undiagnosed HIV and late diagnosis, to build an understanding of the epidemic and time trends at local, regional and national level. Some groups are especially at risk for HIV, including men who have sex with men, injecting drug users, migrants (especially those from countries with higher prevalence), the sexual partners of individuals in all of these groups and the children of HIV-positive mothers. Such sub-populations and/or their risk are often hidden and stigmatised. Special surveys will need to be conducted to find out about the levels of HIV among such groups, their rates of HIV testing, and relevant knowledge, attitudes and behaviour, in order to inform interventions to increase their uptake of HIV testing.

Finally, supplementary data on other sexually transmitted infections, sexual and drug injecting behaviours in the general populations, as well as groups at higher risk of HIV, should also be reviewed.

The aim of surveillance is to build an understanding of the epidemic and time trends at local, regional and national level and among population groups in order to inform policy and intervention efforts. The reporting of new diagnoses of HIV by clinicians and laboratories forms the basis of the understanding of the local and national epidemic in most European countries. These data should be supplemented by other surveillance systems and surveys to provide greater insights into the epidemic within the general population and higher risk groups. The World Health Organization has produced comprehensive guidance on how to plan surveillance of HIV seroprevalence and behavioural risks [48], and a framework for behavioural surveillance is being developed for Europe by the European Centre for Disease Prevention and Control [49].

In most European countries, the HIV epidemic is concentrated in three sub-populations [7]: men who have sex with men, migrants (especially those from high HIV prevalence countries) and injecting drug users. Additional groups at higher risk have been identified in Europe, for example, prisoners, sex workers, and people with sexually transmitted infections and other indicator diseases [50].

It is important to consider ways of extending HIV testing to reach the additional risk groups identified within each country based on national data.

The groups at highest risk of HIV infection are also often disenfranchised and stigmatised, and as a result may not access healthcare services or disclose their risk behaviours when they do. Barriers to HIV testing exist for many of these groups and such barriers need to be understood in different countries and for different sub-populations, with more research being conducted as necessary. Where research on barriers has been conducted and services adapted accordingly, the acceptability of HIV testing for the sub-population concerned increases [32,33].

Although HIV infection in Europe is mainly found in the sub-populations described above, it is also found in the general population. Rates of HIV infection among women attending antenatal care can provide a proxy for the HIV prevalence in the general population as well as identify women at greatest risk when this information is stratified by risk and other demographic information. Surveys about HIV risk in the general population are also useful for comparisons of risk between the sub-populations believed to be at higher risk and the general population [48].

Routinely collected data on HIV-positive individuals are also important to ensure that diagnosed individuals are seen and receiving optimal care. Data from healthcare services other than those that specialise in HIV care, for example sexual health, viral hepatitis and tuberculosis, as well as blood donation [51], may also be useful in building a picture of the national epidemic and access to HIV testing and care. Where resources are limited, sentinel surveillance from a representative sample of HIV-positive individuals and/or the healthcare services they attend may be suitable.

Estimating the proportion of people with HIV who are unaware of their infection (the 'undiagnosed fraction') is important because it allows the scale of the problem to be determined and the success of any programme to be monitored over time. There are many approaches to calculating this measure, each with its own advantages and disadvantages. Measuring late presentation using CD4 count at diagnosis is also an important measure of delays in access to testing and care. Late presentation is associated with higher morbidity and short-term mortality [52]. More detailed information on key epidemiological indicators is provided in Section 3 (Monitoring and evaluation).

2.2 Where to test?

Consider logistics

Plan how the HIV testing programme will be implemented and tackle logistical challenges. These may include how the healthcare system is delivered, whether there is access to free healthcare, the preparedness of community services, counselling and support, how to ensure care pathways are in place for access to HIV treatment, and how confidentiality can be assured.

Increasing the reach of HIV testing, improving its targeting and providing it in new ways is likely to require improvements to existing HIV testing services, changes to other healthcare services and the introduction of completely new services. Examples of this would be introducing the routine offer of an HIV test in a range of healthcare settings or the establishment of outreach HIV testing services for marginalised groups in community settings. The feasibility and appropriateness of such approaches should be assessed and plans will need to be developed to overcome barriers, or to work within existing constraints. Such barriers or constraints may include, for example, the restriction of HIV testing provision to particular professional groups or settings. It will also be necessary to involve those whose commitment and participation will be necessary for success; both civil society and professional groups.

Service planning needs to address the requirements of privacy, confidentiality, the option of anonymity, safety, test accuracy and other quality considerations. It should ensure services are appropriately targeted and that they meet the needs of the groups they target. Policies or measures which contradict the core principles of this HIV testing guidance (Section 1.3) should be reviewed and amended, for example those with implications for testing prisoners or migrants.

The availability of specialist HIV treatment services, as well as other relevant healthcare, counselling and support, should be ensured for those who receive a positive HIV test result and, where needed, those who receive a negative HIV test result. Adequate care pathways should be in place to ensure prompt and appropriate referral and access to such services for all who need them (see Section 2.5).

Make testing available in a variety of settings

Use knowledge of the epidemic and who is at highest risk to make informed decisions about where to offer HIV testing. Also consider any available data about who is currently accessing HIV testing in which settings.

Because of the diversity of needs and the barriers to testing, a range of services should be offered in order to maximise access.

Barriers at the institutional level may hinder efforts to expand HIV testing, including failure to appropriately target the populations most at risk [53] and to provide conveniently located testing sites [54,55]. Offering HIV testing in medical and non-medical settings, in co-operation with non-governmental organisations, including outside normal working hours, can facilitate access and uptake.

It is therefore important to work with affected communities to identify both medical and non-medical settings used by members of the populations most at risk. A systematic approach can be taken to identify specific populations, which settings can be used to reach them, the advantages and disadvantages of each, their relative cost benefits and other considerations.

Whatever the setting, HIV testing programmes should be sensitive and responsive to the needs of the population, and should be established with the involvement of the relevant target group(s) [32,33].

Identify action needed to establish new services or change practice in existing healthcare settings or community services. Evaluate whether regulations that may act as obstacles to testing in community settings, including use of point-of-care tests or the requirement for tests to be performed only by specific professionals, could be relaxed without compromising testing quality.

Dedicated HIV testing services, to provide easy and safe access to HIV testing alone or combined with other tests

Services set up specifically to provide HIV testing for those who wish to have a test should be maintained or expanded, ensuring they are designed to meet the needs of the populations they are intended to serve. Depending on the healthcare system and how HIV care has developed in each country, dedicated HIV testing services may be provided within relevant specialist settings such as sexual health or infectious disease clinics or exist on a stand-alone basis. It is important to ensure that such services are welcoming and culturally appropriate for the population groups which need to use them, including young people, gay men and migrants, and that access to them is not hindered by concerns of confidentiality or cost. The option of anonymous testing should be available. Language services, such as interpreters or multilingual staff, should be provided for migrant populations where needed.

It is likely to be more cost-effective, and convenient for the individual being tested, if the HIV test can be offered in combination with other tests.

Settings where HIV testing should be universally offered

In certain healthcare settings, outlined below, it is beneficial to offer and recommend an HIV test to all those attending (a 'universal offer'). As with HIV testing in other contexts, HIV testing when universally offered still requires informed consent (see Section 2.4 for more on informed consent). However, it is not usually necessary to conduct a full risk assessment of sexual or drug-using practices, except when this is relevant to the specific service, e.g. STI services.

Services for people at high risk, such as STI services or services for injecting drug users

Sexual behaviour is the most common route of transmission of HIV infection. Services which diagnose and treat STIs should therefore routinely offer HIV testing. Risk-based HIV testing has been found to miss a significant proportion of HIV infections [56,57]. The WHO European Regional Office and guidelines issued by International Union against Sexually Transmitted Infections (IUSTI) recommend the routine offer of HIV testing to anyone diagnosed with an STI [2,3].

Services for injecting drug users, including drug treatment, substitution and needle and syringe programmes, present an opportunity to provide HIV testing. Injecting drug users are a particularly vulnerable population with high levels of physical and psychological illness and often chaotic lifestyles [58]. Every country in the European Union offers needle and syringe programmes and all countries include some form of drug treatment programme [59].

Antenatal services, where early intervention can prevent onward transmission of HIV

Antiretroviral therapy during pregnancy is extremely effective in preventing vertical transmission of HIV [24,25]. Antenatal HIV screening programmes, which enable access to such therapy, are a good example of how a clearly defined and well implemented HIV testing strategy can significantly reduce transmissions.

While many European countries currently have policies to routinely offer HIV testing to pregnant women [44], this may not be reflected in practice and some women may remain undiagnosed. A universal offer of HIV testing is recommended in a number of European countries; sometimes integrated with screening for other STIs or blood-borne viruses. Where instituted, this policy has resulted in substantial increases in rates of testing [44]. It is supported by evidence that risk-based antenatal testing misses a substantial proportion of HIV-infected women reporting no risk factors for HIV [60,61].

Where countries have introduced targets for HIV testing and the offer of an HIV test in antenatal care has become routine, the uptake of testing by women has dramatically increased, indicating that the test offer is highly acceptable to both pregnant women and staff [62]. It is noteworthy that, even in countries where it is rarely performed, women find the offer of antenatal HIV screening acceptable [63].

Women who have not been offered an HIV test during pregnancy or who first present to services when already in labour, should be offered an HIV test during labour [24].

Services which undertake the clinical diagnosis and management of HIV indicator conditions

Healthcare services for people with diseases associated with HIV infection (see Appendix B) are likely to serve a population with a higher prevalence of HIV, ranging from three per cent of those with perinatal listeriosis to 94 per cent of those with cryptococcal meningitis [45]. The European AIDS Clinical Society has developed a list of indicator diseases that are associated with a higher than one per cent incidence of HIV infection [45] and recommends a routine offer of HIV testing for all those who present with these conditions (see Appendix B). Including the HIV test as a routine investigation when people with clinical indicator conditions associated with HIV seek healthcare is likely to increase testing rates and reduce late diagnoses [45].

There are, however, barriers to HIV testing for people presenting with certain conditions associated with HIV infection, including stress related to the initial diagnosis, such as tuberculosis, or fear of added stigma of a second illness [32]. Including a routine offer of HIV testing in healthcare services for the clinical diagnosis and management of tuberculosis will therefore help to normalise the test for patients and staff and may contribute to the detection of HIV in those who would otherwise not have been considered at risk [64].

Settings where undiagnosed HIV prevalence is known or estimated to be high

Such settings will vary between countries, and between areas within countries, depending on the local epidemic, the healthcare delivery system and which services are used by populations most at risk of HIV. They may include specific types of setting more likely to be attended by those at higher risk, including prisons, termination of pregnancy services, services for sex workers and youth services. They may also include general healthcare settings such as primary care, emergency departments and medical admissions units in geographical areas where HIV prevalence is high.

Areas with a high level of diagnosed HIV prevalence are also likely to have a high level of undiagnosed prevalence. This principle underpins the recommendation in UK guidelines to expand HIV testing in local areas of high diagnosed prevalence, specifically in general practice and general medical admissions to hospital. Research in the United States indicates that testing in general healthcare settings may be cost-effective where there is a high (greater than 1 per 1000 population) undiagnosed prevalence of HIV [65].

All other healthcare settings, where people should be able to request testing or where professionals should be ready to offer it and be vigilant to when it is needed

People should be able to receive an HIV test when they request it in any general medical setting, such as primary care, sexual and reproductive health services and youth clinics.

Professionals in all healthcare settings should also be vigilant to the possibility of undiagnosed HIV infection and aware of the risk factors and clinical indicators for HIV. They should be ready and able to offer HIV testing when it is needed.

Testing sites in the community, including outreach services, to reach people at higher risk of HIV who may be hidden or marginalised and not in touch with traditional healthcare services

Testing in the community is a broad term that encompasses services providing HIV testing, usually for specified groups at higher risk of HIV, in non-traditional or non-medical settings such as Gay Pride events, mobile testing buses or homeless shelters. It may be provided as a dedicated HIV testing service or as part of broader range of services (health or otherwise) for the target group.

Testing in community settings may reach greater numbers of people at high risk of HIV. For example, higher risk injecting drug users who do not attend drug treatment programmes may be reached through outreach services such as needle exchange programmes. HIV testing services for migrants from areas of high HIV prevalence can be grounded in outreach and community mobilisation projects, building on existing structures and partnerships [66]. To overcome barriers to access it is important to ensure that the features of such services, for example their location and opening hours, are adapted to the needs and lifestyles of the groups they aim to reach.

Such services should be established with the involvement of the targeted sub-populations.

When developing community-based HIV testing services it is also important to engage with civil society organisations that serve groups at higher risk of HIV infection [32,33] and to ensure good clinical governance of community testing services, with clear referral pathways for confirmation of reactive results and access to treatment, care, counselling and support, and to prevention services.

2.3 When to test?

Provide guidance on testing frequency

More frequent testing is advisable for people who have ongoing exposure to high risk. For example, some countries recommend that men who have sex with men should be tested annually, or more often depending on sexual behaviour. Current guidance from the European Monitoring Centre for Drugs and Drug Addiction (EMCDDA) recommends regularly offering tests to injecting drug users at least once every 6 to 12 months [67].

Repeat HIV testing may assist early detection of HIV infection in at-risk populations and individuals with repeated episodes of unsafe behaviour. However, it is not clear whether repeat negative tests reinforce risk behaviour or whether repeat testers are more likely to correctly identify and disclose risk behaviours. Retrospective studies have characterised repeat testers as more likely to engage in high risk behaviour between tests; this is especially true for men who have sex with men [68–72]. Evidence-based counselling, with continuous quality assurance, is a measure that may be used to counteract the potential negative effects of repeat testing on risk behaviour.

Where guidance on repeat testing for groups at higher risk of HIV exists, this is based on expert advice, accepted good practice and modelling studies. The United States, Australia, France, Norway and the UK recommend annual testing of all individuals in specified groups at higher risk.

The cost-effectiveness of repeat testing of groups at higher risk will depend on the HIV incidence and prevalence within the sub-population. Economic modelling has not found annual testing to be cost-effective even in populations with high (3 per cent) prevalence [73]. However, a French evaluation of HIV testing strategies found both a one-off HIV test in the general population and regular HIV testing in populations at high risk and in areas of high prevalence to be cost-effective [74].

2.4 How to test?

Raise public awareness

To seek and accept HIV testing, the public, and especially groups at higher risk of HIV, need to understand its benefits. A strategic approach to communication is needed, using a range of different channels. Visible and high-level support from opinion formers, including politicians, community leaders and celebrities, and supportive and accurate coverage in the media, can all be used to raise awareness.

Ensuring that accurate information is available about HIV, its transmission routes, its prognosis and how treatments affect it, should be part of a national HIV testing strategy. A range of communication channels should be used, including local healthcare professionals and community-based organisations as well as traditional and electronic media, and communication strategies should be adopted to reach the most-at-risk populations [75]. Such interventions need to be tailored to needs and culturally appropriate for their target audiences.

Responsible media reporting of HIV should be promoted and, where possible, people in the public eye can assist in preparing the public to consider the benefits of testing for HIV. It is also useful to consider implementing targeted public awareness campaigns aimed at populations most at risk of HIV [36,75,76].

Information efforts need to be maintained over time in order to have a sustained impact as, although short-term media campaigns have resulted in significant immediate increases in HIV testing, a sustained impact is not achieved once a campaign ends [36].

Ensure confidentiality

Confidentiality is a fundamental principle of all healthcare but because of the stigma attached to HIV and the behaviours through which it may be transmitted, it is critically important for HIV testing. Relevant professional guidance and national legal requirements should be followed. A lack of confidence in confidentiality among people at risk may act as a barrier to accessing HIV testing services.

Clear policies on confidentiality, and publicity about the policies in settings providing testing, can help to overcome this barrier.

The importance of confidentiality and how to ensure it is highlighted in the WHO European Region policy framework on scaling up HIV testing and counselling [2] and the WHO/UNAIDS guidance on provider-initiated testing [4].

In migrant populations confidentiality concerns are particularly relevant [36]. A fear frequently observed in migrant populations is that an HIV diagnosis will have negative consequences for immigration or asylum applications [29,30,37,77]. Fear of the negative social consequences of a positive diagnosis (stigma, discrimination, rejection) has been highlighted as more important than fear of death or illness among all populations, including migrants and men who have sex with men [34].

HIV testing should always be offered and discussed in privacy. The option of anonymous testing should be available.

There is evidence that individuals choosing anonymous testing have a high burden of HIV [78]. This approach can remove a barrier to testing for disenfranchised populations such as uninsured individuals, non-residents, undocumented migrants, injecting drug users, men who have sex with men and prisoners, especially when provided free of charge.

Raise professional awareness and train the workforce

While activities to raise public awareness will also reach professionals, training can be used to raise their awareness and increase their confidence and competence to offer HIV testing.

HIV testing can be offered by any appropriately trained and skilled healthcare worker, and expanding HIV testing will require a wider workforce which is confident and competent to offer it. With appropriate training and quality assurance, non-healthcare workers may also offer HIV testing. Members of the workforce need to understand the benefits of HIV testing and overcome the barriers which inhibit their ability and willingness to offer it. These include lack of confidence in raising the subject, difficulties in talking about sex or stigmatised behaviours, anxiety about giving a positive result and discriminatory attitudes towards people at risk or affected by HIV.

Important barriers to HIV testing identified at the provider and institutional level include lack of staff training and the perception that HIV testing can only be offered and performed by specialists. Education and training are therefore needed to ensure that healthcare and other relevant workers are able to offer the test appropriately and for the right reasons, and that people at risk of HIV are made to feel able to come forward for testing or to accept the offer of a test. HIV testing should be part of the general medical curriculum for all doctors in training.

Research into patients' barriers to testing has highlighted the importance of the healthcare worker's recommendation in influencing their decision to test [77,79]: making the test offer more routine and the process more like that for other diagnostic tests will contribute to a reduction in HIV stigma [63,80].

To motivate healthcare workers to offer the test, it is important that they understand the benefits of HIV testing. Staff training should include a mix of information and skills development which includes details of the national HIV epidemic, and relevant guidance on consent and confidentiality. Training should be audited as part of good clinical governance, and attendees at services offering HIV testing need to be made aware that staff are appropriately trained.

The requirement to conduct a full risk assessment of sexual or drug using practices has been highlighted as a barrier to HIV testing. This is because many healthcare professionals who do not specialise in HIV or sexual health are unwilling to conduct risk assessments for fear of embarrassing or offending people who do not fit the usual HIV risk profile, even where such assessments have been recommended as good practice. This often results in the test not being offered [77,81]. However, in some settings where an HIV test is universally offered, such a risk assessment is not usually necessary (see Sections 2.2 and 2.4).

Pre-test discussion

Brief pre-test discussion, covering the benefits of testing and the practical arrangements for taking the test and giving results, has been shown to be acceptable and effective in helping to increase testing uptake. The main purpose is to ensure informed consent which should be documented but does not have to include signed written consent. This is in line with other medical investigations and is part of the normalisation of HIV testing. A detailed sexual or injecting history is not required before offering an HIV test. However, for certain individuals, or in settings where sexual health and/or drug use is within the scope of the services, a brief risk assessment or more extensive pre-test counselling may be indicated, e.g. in case of continued risk exposure. This should always be available and staff should know how to refer to skilled counsellors.

As with any medical test or investigation, people need to be able to make an informed decision about whether to undergo an HIV test. The model of pre-test counselling traditionally used included an in-depth discussion about an individual's risk behaviour and an assessment of their likelihood of being infected. However, this can be a barrier to HIV testing if those offering the test feel unable to carry out such a risk assessment due to lack of appropriate training, personal discomfort with discussing sexual behaviour or drug use, or fear of offending or embarrassing the person offered testing.

Pre- and post-test 'counselling' requirements can be seen by health professionals as a barrier to HIV testing [82–85], implying the need for specialist counselling skills or the presence of a qualified counsellor. To reduce this barrier and to help normalise the HIV test, there has been a move away from in-depth pre-test counselling towards shorter pre-test discussion [3]. Brief pre-test discussion (sometimes referred to as 'pre-test information') has been shown to be acceptable to people taking the HIV test and is not detrimental to testing uptake [86]. This covers the essentials such as the voluntary nature of the test, the benefits of testing, the practical arrangements for taking the test and details of how the result will be given.

Removing the need for written consent has also been shown to be effective in increasing rates of testing [87,88].

It is helpful to provide further information for those who need it about other aspects of HIV infection, as lack of information can be a barrier to testing [37].

For those offered a test on clinical grounds, a detailed sexual history is not required before offering an HIV test, nor is it necessary to obtain information about current or previous drug injecting. However, it is important to be

aware that some people may present with more complex needs. This will require a more in-depth discussion and access to high-quality counselling if needed. Such individuals may also benefit from the HIV prevention messages that such a discussion covers.

In some HIV testing services which target the populations most at risk, such as those in the community, a brief risk assessment may be a routine part of the pre-test discussion. Such services can be important places for identifying individuals with ongoing high risk behaviour and referral should be available to high-quality prevention services, counselling and support (see Section 2.5).

Use appropriate testing technologies

Identify the HIV tests available and assess their respective benefits for testing in different contexts, including rapid (point-of-care) screening tests. Testing technology is constantly evolving and expert advice should be sought to keep the choice of tests under regular review. All reactive screening tests (including point of care screening tests) should be verified using more specific confirmatory tests in accordance with WHO and European guidelines.

National guidelines for applying a minimum standard of quality assurance for diagnostic testing based on WHO and European guidelines are essential to ensure high-quality practice and methodological standardisation and reliability [3,89].

The use of an enzyme-linked immunoassay (EIA) followed by confirmatory Western blot or line-blot assay is currently the gold standard minimum laboratory algorithm for diagnosing HIV infection. Preferably, fourth-generation screening assays that simultaneously test for anti-HIV-1 antibodies and HIV-1 p24 antigen as well as anti-HIV-2 antibodies are recommended to be used as serological HIV screening tests [90,91]. For the fourth-generation tests, a separate confirmatory test for the antigen component of the test is necessary.

Rapid HIV tests, also known as point of care tests (POCT), may improve HIV testing acceptability and uptake in several key settings. These include busy clinical settings, where they can increase uptake of HIV testing when offered [92], for example among people who are unwilling to have blood taken, or where an HIV test result is needed urgently; and community testing settings serving high-risk populations where traditional venepuncture is not possible or where quick turnaround of test results is desirable [93,94]. Rapid testing has been shown to be acceptable and feasible in community settings [55,95–100] and has the advantage of increasing the proportion of test results that are passed on to testing recipients [101,102].

Rapid HIV testing has been shown to be acceptable to women in antenatal screening programmes and may have a useful role in labour and delivery settings for women who previously declined standard HIV testing [103]. Rapid HIV testing is also increasingly being offered by STI services in some countries as this is preferred by some attendees [104,105]. It may also be useful following blood exposure accidents.

There is conflicting evidence on the acceptability of rapid testing compared with standard testing among injecting drug users [106–108]. However, with high rates of failure to return for results of the standard test, rapid testing may be useful in ensuring receipt of result and entry into care [109].

The performance characteristics of rapid tests differ from those of standard EIA tests and these should be taken into account when assessing the suitability of rapid testing for use in any particular setting. Such characteristics include specificity, sensitivity, window period and ease of use in the setting. Both saliva and blood tests may be used as screening tests, as long as the tests have been issued a CE-mark for the sample material.

Rapid testing should be quality-assured, with established links to the laboratory. The United States CDC and WHO have issued joint quality assurance guidelines for rapid testing which could be used or adapted for quality assurance in European countries [89].

Always give results

Every effort should be made to ensure that people who have had an HIV test are informed of the result, whether positive or negative. When giving positive results, ensure staff are available to provide post-test counselling and that links to appropriate HIV treatment and support services are also in place for referral. People at high risk of HIV who receive a negative test result may also benefit from counselling and referral to appropriate prevention services.

It can take up to two weeks for the result of a standard laboratory HIV test to become available. Therefore, unless a rapid HIV test is used with results available at the same visit, an appointment should be made for people to receive test results.

Positive results should always be given in person and preferably by the healthcare worker who performed the test. Arrangements need to be made for results to be given face to face, in privacy and with sufficient time for discussion.

People found to be HIV-positive should be given details of local specialist services and, prior to the result being given, there need to be clear pathways in place for onward referral. More detailed post-test discussion (including assessment of disease stage, consideration of treatment, partner notification and need for psychosocial support) should usually be performed by the HIV specialist team and those diagnosed with HIV should be fully informed about this process (see also Section 2.5).

It may be possible to provide negative HIV test results using methods such as telephone appointment, SMS message or post if this will help to streamline the process [110] and to reduce the number of occasions on which patients do not return for test results [111–113]. However, giving a negative result in person provides an opportunity to engage in sexual health promotion and offer HIV prevention messages especially for those at higher risk of infection.

2.5 Ensuring access to HIV treatment, care and prevention

Access to antiretroviral therapy

It is essential for all HIV testing programmes to have clear mechanisms to ensure that people who test positive are integrated into HIV treatment and care. There should be universal access to antiretroviral therapy across Europe. Inability to afford the cost should not prevent access to treatment, and solutions need to be found to overcome this barrier to universal access.

The 2001 UNGASS *Declaration of Commitment on HIV/AIDS* and the 2004 *Dublin Declaration on Partnership to Fight HIV/AIDS in Europe and Central Asia* commit EU Member States to providing universal access to comprehensive HIV prevention, treatment, care and support programmes by 2010.

Referral pathways should be in place from all HIV testing sites to ensure that people receive a specialist consultation promptly after receiving a positive HIV test result. This consultation should include an assessment of when to start antiretroviral therapy and needs for other health and social care and support.

Access to care is important to ensure that diagnosed individuals benefit from antiretroviral therapy and from other health, social care and support services. It is recommended that HIV testing strategies include a requirement for prompt access to specialist care. For example, UK guidelines recommend that an individual testing HIV-positive for the first time be seen by a specialist at the earliest possible opportunity, preferably within 48 hours and certainly within two weeks of receiving the result [114]. It is therefore important to ensure that access to treatment is not hindered by structural factors such as healthcare system organisation or legislation that restricts access for populations at higher risk, in particular migrant communities.

Where HIV testing is carried out in non-traditional settings, such as acute care settings or community testing sites, strong links to HIV specialist services, including dedicated HIV counsellors or HIV clinic appointments, may facilitate entry into HIV care.

Access to psychosocial support and prevention services

Psychosocial support should be immediately accessible following a positive test result.

Services performing HIV testing should have well established links with providers of psychosocial support in order to ensure referral is possible without delay. Appropriately trained personnel from a variety of organisations (e.g. community organisations, social services teams) may play a useful role in providing this.

The fact that many people with a newly diagnosed HIV infection are migrants creates particular counselling and support needs, and special efforts need to be made to overcome language and cultural barriers for these populations.

For people who test positive, referral to specialist care should include access to support for the prevention of further transmission of HIV.

This includes strategies for partner contact tracing and partner referral (also known as partner notification) as well as counselling and support for behaviour to prevent transmission to sexual and/or drug using partners [115–117]. Strategies to encourage regular testing of partners initially found HIV-negative should also be addressed.

For people who test negative, referral to counselling and support for HIV prevention should also be available where there is significant ongoing risk of exposure or upon request.

Such counselling needs to be evidence-based, provided by those with appropriate skills and training and subject to quality assurance.

3 Monitoring and evaluation

Monitoring and evaluation (M&E) is an essential component of an HIV testing programme and ensures that the programme is fit for purpose and provides high-quality HIV testing.

The process relies on the collection of good quality data and timely dissemination of results to key stakeholders. A well designed M&E system will inform policies, improve the quality and effectiveness of interventions and therefore guide future allocation of resources. National surveillance data, including new diagnoses, the proportion of individuals who present late and an estimate of the number of undiagnosed infections, are important for monitoring the impact of a programme. Expanding testing in new settings will require robust M&E to ensure high-quality HIV testing reaches the populations most at risk.

The success of local interventions to promote HIV testing can be assessed according to five criteria: Feasibility; Acceptability; effectiveness and Cost-effectiveness; Target populations are reached; and Sustainability (FACTS). Clear, well defined and measurable indicators can assist in monitoring these criteria and provide a standard method of reporting findings at local, national and international levels.

The monitoring of an HIV testing programme refers to the ongoing collection of data which can be examined at any point in the programme and used to determine or inform changes as time progresses. Evaluation refers to the systematic analysis of data collected from the programme until a set time point has been reached. The information collected should be informed by, and closely reflect, the aims and objectives of the HIV testing programme so that it becomes an integral part of the performance management of the programme. Data from M&E systems should be used in the quality assurance and quality improvement of HIV testing (WHO, in press). Robust M&E strategies will therefore ensure that the HIV testing programme can evolve, develop and remain fit for purpose.

Monitoring and evaluation relies upon the collection, analysis and interpretation of good quality, standardised data and the timely dissemination of results to key stakeholders. Ideally, an M&E framework should be developed during the planning stages of an HIV testing programme addressing the following: how the data systems will assess programme objectives; how data will be collected; what indicators will be used; who will be responsible for data collection; and how data will be disseminated.

The information will need to be gathered from a range of sources and settings and particular consideration should be given to using data collection systems which are already in place. However, lack of data is not a reason to delay developing and implementing a programme to increase uptake of testing. A strategy for improving HIV testing should be based on the best available evidence and expert consensus and include plans for the development of new data systems and/or surveys.

3.1 Monitoring and evaluation at the national and international level

Indicators are defined measures which are formed from data collected as part of the monitoring and evaluation. The selection of indicators will need to be considered before the implementation of the programme and wherever possible build on current measures that are being collected. The indicators must be adequate and appropriate to monitor and evaluate an HIV testing programme, but at the same time not overburden front-line staff.

Using indicators at the national level which are consistent with those from other countries enables a comparison of the situation at an international level. This allows countries to share knowledge on strategies that have worked and compare the means of programmes' successful implementation. A number of international documents provide core indicators for M&E of HIV programmes:

- The United Nations General Assembly Special Session on HIV/AIDS (UNGASS) core indicators (UNAIDS, 2009) [118]
- Implementing the Dublin Declaration on Partnership to fight HIV/AIDS in Europe and Central Asia (ECDC, 2010) [1]
- WHO Handbook for improving HIV testing and Counselling Services (WHO, in press) [119]
- The WHO Guide to Monitoring and Evaluating National HIV Testing and Counselling Programmes (WHO, in press) [120]
- ECDC Mapping of HIV/STI behavioural surveillance (ECDC, 2009) [121].

In developing and selecting indicators, it may be helpful to divide those indicators that measure input (e.g. infrastructure, financial resources available, policies), process (e.g. human resources, training, adequate and appropriate tests available), outputs (e.g. coverage of programme, number of people approached), outcomes (e.g.

number of tests undertaken) and impact (e.g. reduction in number of undiagnosed infections or proportion of HIV infections diagnosed late). These categories can also be collapsed simply into process and outcome measures (see Appendix A, Table 1). For each indicator selected for use, a clear rationale and understandable definition will need to be agreed by key stakeholders and a standardised method of data collection described. A list of examples for indicators for use at national/international level is shown in Appendix A, Table 1.

Data from national HIV surveillance systems should form an integral part of M&E of HIV testing programmes. Surveillance data should be used in the early stages of planning an HIV testing programme as well as for monitoring the impact of HIV testing programmes. Reports of new HIV diagnoses and prevalence surveys will help identify groups at highest risk of HIV (see Section 2.1). Analysis of these data over time provides insights into how large-scale initiatives are impacting on the epidemiology of HIV within the country as the number of new HIV diagnoses reflects patterns of both transmission and of HIV testing. These data are best presented by appropriate socio-demographic variables (e.g. age, sex or ethnicity) as well as most-at-risk groups (e.g. men who have sex with men, injecting drug users and migrants from high prevalence countries).

Analyses of routine HIV data can be supplemented by second generation surveillance such as STI diagnoses and behavioural surveys. Regular behavioural surveys provide vital information to ascertain the success of programmes in increasing the uptake of HIV testing, especially in the most-at-risk groups.

The proportion of new HIV cases that have been diagnosed late (i.e. after a point at which treatment should have been initiated – currently set at a CD4 count of less than 350 cells/mm³ or presenting with AIDS [13]) can be used to assess the effectiveness of HIV testing programmes. If these programmes are successfully reaching those individuals with undiagnosed HIV infection, over time the number and proportion of individuals diagnosed late with HIV should fall.

The proportion of HIV infected individuals who are unaware of their infection (the undiagnosed fraction), where available, is an important indicator which allows assessment of the true extent to which an HIV testing programme is reaching those who are already infected. As assessment of this proportion can be resource intensive, expensive and can raise ethical issues. Consideration should be given to conducting repeatable surveys among populations most at risk or restricting the surveillance to sentinel sites.

3.2 Assessing HIV testing initiatives at the local level

Reaching the population most at risk will require expanding testing in a number of clinical and community settings. It is critical that local HIV testing initiatives are subject to vigorous M&E to assess their success and inform future HIV testing policies and programmes. The success of local HIV testing initiatives can be assessed using the FACTS criteria.

Feasibility. HIV testing programmes need to be implemented in feasible and appropriate settings, ensuring that adequate resources and staff are provided to implement the programme. Monitoring numbers and proportions of clients who are offered a test will provide information on how the initiative is working in practice and where there may be shortfalls in staff or resources. Audits of referral pathways are needed to ensure results are returned to patients and that those who test positive receive appropriate care and counselling in a timely manner.

Acceptability. The offer of an HIV test must be acceptable to staff and the specific target group. It is important that the offer of a test is voluntary and confidential and that staff feel adequately trained to offer the HIV test with specialist backup if required. Surveys to assess the satisfaction of persons offered an HIV test and staff providing the service will be important in the early phase of implementation and may identify barriers to testing. Surveys should include a question on patient satisfaction and perceived stigma. Qualitative data from staff and patients derived from focus groups, interviews or diaries may also be used. These methods will provide an opportunity to collate opinions about the type of test used, the methods of providing results and referral pathways as well as attitudes towards the routine offer of the HIV test. The information can be used to modify local procedures for HIV testing, helping to maximise the offer and uptake of HIV tests.

Effectiveness and Cost-effectiveness. A critical component of the success of an initiative is its ability to detect previously undiagnosed infections. The HIV positivity rate is a measure of the number of previously undiagnosed HIV infections detected among the population tested and is the key indicator for assessing effectiveness of the initiative. Trends in HIV positivity rates within a specific setting (e.g. emergency departments) will determine whether testing in this setting remains effective. It is also important to determine whether the resources and staff costs required to establish and sustain the programme are proportional to the results. The HIV positivity rate combined with the cost of the programme will assess its cost-effectiveness. Studies in the United States indicated that HIV testing is cost-effective in a setting where at least 1 in 1000 people tested are found to be infected with HIV (and were not previously diagnosed) [65,73,122]. A similar threshold for the European context is needed.

Target populations are reached. Measuring the uptake of testing and HIV positivity rates in the populations most at risk (e.g. men who have sex with men and injecting drug users) will provide a measure of how effective the initiative is at reaching target populations and hence whether the initiative is accessible to that population

group. Likewise, positivity rates among groups most at risk will provide information on whether the initiative is serving the most appropriate population groups.

Sustainability. HIV testing programmes need to be set up in a sustainable manner. Ongoing systematic review of M&E data by key stakeholders will help assess whether the programme remains fit for purpose, or needs to develop or evolve. For example, declining numbers of offers, or uptake, of HIV tests in the target population may indicate the need to promote testing to this group and reinvigorate interest among, and training of, staff involved in the programme. Setting targets and goals as part of an HIV strategy can provide incentives for local health services to achieve and maintain high rates of HIV testing.

Examples of indicators for each of the FACTS criteria are provided in Appendix A, Table 2.

3.3 Making it work

It is important that the responsibilities for the maintenance of the M&E system are clearly demarcated and assigned at local and national levels. Those teams responsible for M&E systems need adequate resources and staffing and to have clear lines of communication between major stakeholders.

Data systems will need to be regularly reviewed to ensure they are fit for purpose. It may be useful to assess their fitness using the SMARTER criteria: specific, measureable, attainable, relevant, timely, evaluated and re-evaluated.

It is vital to the success of an HIV testing programme that patient confidentiality, and the perception of confidentiality, are preserved. This need must be balanced in M&E systems so that enough individual data are kept to allow meaningful interpretation but not to identify an individual. Thus, alongside assurances about the release of data and security of databases, codes may assist in creating confidential reporting systems [123].

A plan to disseminate results to key stakeholders in a regular and timely manner needs to be agreed. Where possible, local initiatives which form part of a larger national strategy should be rigorously evaluated and written up as reports and peer-reviewed articles to inform the ongoing development and refinement of the HIV testing programme.

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Appendix A

Table 1: Monitoring and evaluation at the national/international level

	Examples of indicators	References
Process indicators	Existence of national testing policies and guidelines that are consistent with international standards (WHO/AIDS)	UNGASS (as part of National Composite Policy Index), WHO M&E guide
	% men and women who had an HIV test in the last 12 months and know the results	UNGASS, WHO M&E guide
	% of most-at-risk populations (MSM, IDU, migrants) who had an HIV test in the last 12 months and know their results	UNGASS, WHO M&E guide
	% of pregnant women who have been tested for HIV in the last 12 months and know their results	WHO M&E guide
	% of TB patients who have been tested for HIV in the last 12 months and know their results	WHO M&E guide
	% of STI patients who have been tested for HIV in the last 12 months and know their results	ECDC
	Numbers and proportions of persons offered testing stratified by setting (particularly, anonymous testing sites and primary care sites)	
Outcome indicators	Total number of new diagnoses stratified by most-at-risk populations including unknowns	Dublin Declaration
	Number and % of new diagnoses which are diagnosed late with CD4 <200 (overall and by most-at-risk population) Number and % of new diagnoses which are diagnosed late with CD4 <350 (overall and by most-at-risk population) Number and % of new diagnoses which are diagnosed late with AIDS at presentation (overall and by most-at-risk population)	Dublin Declaration
	% new diagnoses who are recently infected (RITA or other seroconversion algorithms)	
	% of newly diagnosed individuals who are successfully transferred to care within three months (overall and by most-at-risk populations)	WHO M&E guide
	Total number and proportion of undiagnosed infections	
	Number and proportion in most-at-risk groups of undiagnosed infections	

Table 2: Monitoring and evaluation in specific settings
Examples of indicators to assess local HIV testing initiatives using the FACTS criteria

Criteria for project success	Examples of indicators
F Feasibility	Number and % of persons offered HIV testing
	% newly diagnosed individuals who are successfully transferred to care within three months
A Acceptability	Number and % uptake of an HIV test (overall and among populations most at risk)
	% of patients agreeing that the offer of an HIV test in this setting is acceptable
	% of patients willing to disclose risk behaviour
	% of patients satisfied with the patient information provided
	% of staff reporting barriers to offer an HIV test in this setting
	% of staff reporting specific training needs
E Effectiveness and cost effectiveness	Positivity rate (overall and among populations most at risk)
	Staff costs associated with intervention
	Resource costs associated with intervention
	Outcome of cost-effectiveness model
T Target populations reached	% of most-at-risk populations who had an HIV test in the last 12 months and know their results
	Positivity rate among most-at-risk populations tested in the setting
S Sustainability	Number and % uptake of an HIV test (overall and among populations most at risk)
	Staff costs associated with intervention
	Resource costs associated with intervention

Appendix B

Clinical indicator conditions for HIV infection

Table 3: AIDS-defining illness and other illnesses strongly associated with immunodeficiency in HIV-infected populations

Candidiasis of the bronchi, trachea or lungs	Kaposi's sarcoma
Candidiasis (oesophageal)	Lymphoma, Burkitt's Lymphoma (immunoblastic)
Cervical cancer (invasive)	Lymphoma (primary) of the brain
Coccidioidomycosis (disseminated or extrapulmonary)	<i>Mycobacterium avium</i> complex or <i>Mycobacterium kansasii</i> (disseminated or extrapulmonary)
Cryptococcosis (extrapulmonary)	<i>Mycobacterium tuberculosis</i> , any site (extrapulmonary or pulmonary)
Cryptosporidiosis, chronic intestinal (>1 month's duration)	<i>Mycobacterium</i> , other species or unidentified species (disseminated or extrapulmonary)
Cytomegalovirus disease (other than liver, spleen or nodes)	<i>Pneumocystis jirovecii</i> pneumonia
Cytomegalovirus retinitis (with loss of vision)	Pneumonia (recurrent)
Encephalopathy (HIV-related)	Progressive multifocal leukoencephalopathy
Herpes simplex: chronic ulcer(s) (>1 month's duration); or bronchitis, pneumonitis or oesophagitis	<i>Salmonella</i> septicaemia (recurrent)
Histoplasmosis (disseminated or extrapulmonary)	Toxoplasmosis of the brain
Isosporiasis (chronic intestinal (>1 month's duration))	Wasting syndrome due to HIV

Adapted from: Gazzard B, Clumeck N, d'Arminio Monforte A, Lundgren JD. Indicator disease-guided testing for HIV—the next step for Europe? *HIV Med.* 2008 Jul;9 Suppl 2:34-40. Review.

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HIV prevalence in patients with clinical indicator conditions in Europe

Table 4: Prevalence of HIV in patients presenting with various indicator diseases (European studies)

Disease	HIV prevalence	References
1 Candidiasis	6–23%	Tortorano AM, Biraghi E, Astolfi A, Ossi C, Tejada M, Farina C, et al; FIMUA Candidemia Study Group. European Confederation of Medical Mycology (ECMM) prospective survey of candidaemia: report from one Italian region. <i>J Hosp Infect</i> 2002; 51: 297–304. Tortorano AM, Rigoni AL, Biraghi E, Prigitano A, Viviani MA; FIMUA-ECMM Candidaemia Study Group. The European Confederation of Medical Mycology (ECMM) survey of candidaemia in Italy: antifungal susceptibility patterns of 261 non-albicans <i>Candida</i> isolates from blood. <i>J Antimicrob Chemother</i> 2003; 52: 679–682.
2 Herpes zoster	Unknown	
3 Fungal infections of the skin		
Cryptococcosis	77%	Dromer F, Mathoulin-Pélissier S, Launay O, Lortholary O; French Cryptococcosis Study Group. Determinants of disease presentation and outcome during cryptococcosis: the CryptoA/D study. <i>PLoS Med</i> 2007; 4: e21.
4 Oral manifestations of HIV disease	Unknown	
5 Sexually transmitted infections		
Hepatitis B	Unknown	
Hepatitis C	8–59%	Bini EJ, Currie SL, Shen H, Bräu N, Schmidt W, Anand BS, et al; VA HCV-001 Study Group. National multicenter study of HIV testing and HIV seropositivity in patients with chronic hepatitis C virus infection. <i>J Clin Gastroenterol</i> 2006; 40:732–739. Cacoub P, Renou C, Rosenthal E, Cohen P, Loury I, Loustaud-Ratti V, et al. Extrahepatic manifestations associated with hepatitis C virus infection. A prospective multicenter study of 321 patients. <i>The GERMIVIC. Groupe d'Etude et de Recherche en Médecine Interne et Maladies Infectieuses sur le Virus de l'Hépatite C. Medicine (Baltimore)</i> 2000; 79: 47–56. Posthouwer D, Makris M, Yee TT, Fischer K, van Veen JJ, Griffioen A, et al. Progression to end-stage liver disease in patients with inherited bleeding disorders and hepatitis C: an international, multicenter cohort study. <i>Blood</i> 2007; 109: 3667–3671. Raguin G, Rosenthal E, Cacoub P, Veyssier P, Piette JC, Micoud M. Hepatitis C in France: a national survey in the Departments of Internal Medicine and Infectious Diseases. <i>The GERMIVIC (Joint Study Group on Hepatitis C virus of the French National Society of Internal Medicine and the French Society of Infectious Diseases). Eur J Epidemiol</i> 1998; 14: 545–548.
Lymphogranuloma venereum	74%	Jebbari H, Alexander S, Ward H, Evans B, Solomou M, Thornton A, et al; UK LGV Incident Group. Update on lymphogranuloma venereum in the United Kingdom. <i>Sex Transm Infect</i> 2007; 83: 324–326.
6 Pregnancy		
France	0.34%	Hudson C, Bergenstrom A, Bell E, McCann E, Sherr L. The dilemma of antenatal HIV testing: what goes on in the European Community? <i>J Roy Soc Med</i> 1999; 92:273–276.
Greece	0.1%	Hudson C, Bergenstrom A, Bell E, McCann E, Sherr L. The dilemma of antenatal HIV testing: what goes on in the European Community? <i>J Roy Soc Med</i> 1999; 92:273–276.
Italy	0.1–0.3%	Hudson C, Bergenstrom A, Bell E, McCann E, Sherr L. The dilemma of antenatal HIV testing: what goes on in the European Community? <i>J Roy Soc Med</i> 1999; 92:273–276.
Netherlands	0.3%	Cocu M, Thorne C, Mătușă R, Tica V, Florea C, Asandi S, Giaquinto C. Mother-to-child transmission of HIV infection in Romania: results from an education and prevention programme. <i>AIDS Care</i> 2005; 17:76–84.
Romania	0.2%	Simpson W, Johnstone F, Goldberg D, Gormley S, Hart G. Antenatal HIV testing: assessment of a routine voluntary approach. <i>Br Med J</i> 1999; 318: 1660–1661.

Disease	HIV prevalence	References
Scotland	0.2%	Hudson C, Bergenstrom A, Bell E, McCann E, Sherr L. The dilemma of antenatal HIV testing: what goes on in the European Community? <i>J Roy Soc Med</i> 1999; 92:273–276.
UK	0.01–0.26%	Hudson C, Bergenstrom A, Bell E, McCann E, Sherr L. The dilemma of antenatal HIV testing: what goes on in the European Community? <i>J Roy Soc Med</i> 1999; 92:273–276.
7 Respiratory infections		
Tuberculosis	10–25%	Melzer M, Warley A, Milburn H, O'Sullivan D, Barker RD, Hutchinson D, et al. Tuberculosis and HIV seroprevalence in Lambeth, Southwark and Lewisham, an area of South London. <i>Respir Med</i> 2003; 97: 167–172. Scotto G, Saracino A, El-Hamed I, Iannece MD, Geraci S, Palumbo E, et al. Epidemiology of tuberculosis in immigrant patients hospitalised in Infectious Diseases Units in Italy: multicentric study. <i>Infez Med</i> 2004; 12:245–251 [Article in Italian]. Tattevin P, Casalino E, Fleury L, Egmann G, Ruel M, Bouvet E. The validity of medical history, classic symptoms, and chest radiographs in predicting pulmonary tuberculosis: derivation of a pulmonary tuberculosis prediction model. <i>Chest</i> 1999;115: 1248–1253.
Community-acquired pneumonia	19–24%	Goss CH, Rubenfeld GD, Park DR, Sherbin VL, Goodman MS, Root RK. Cost and incidence of social comorbidities in low-risk patients with community-acquired pneumonia admitted to a public hospital. <i>Chest</i> 2003;124: 2148–2155. Vallès X, Marcos A, Pinart M, Piñer R, Marco F, Mensa JM, et al. Hospitalized community-acquired pneumonia due to <i>Streptococcus pneumoniae</i> : has resistance to antibiotics decreased? <i>Chest</i> 2006; 130:800–806.
8 Neurological disease		
Meningitis (cryptococcosis)	68–94%	Dromer F, Mathoulin-Pélissier S, Launay O, Lortholary O; French Cryptococcosis Study Group. Determinants of disease presentation and outcome during cryptococcosis: the CryptoA/D study. <i>PLoS Med</i> 2007; 4: e21. Tintelnot K, Lemmer K, Losert H, Schär G, Polak A. Follow-up of epidemiological data of cryptococcosis in Austria, Germany and Switzerland with special focus on the characterization of clinical isolates. <i>Mycoses</i> 2004; 47: 455–464. ECMM. European Confederation of Medical Mycology (ECMM) prospective survey of cryptococcosis: report from Italy. <i>Med Mycol</i> 2002; 40: 507–517.
Perinatal listeriosis	3%	Nolla-Salas J, Bosch J, Gasser I, Vinas L, de Simon M, Almela M, et al. Perinatal listeriosis: a population-based multicenter study in Barcelona, Spain (1990–1996). <i>Am J Perinatol</i> 1998; 15: 461–467.
9 Gastroenterology		
Nosocomial diarrhoea	10–12%	Bauer TM, Lalvani A, Fehrenbach J, Steffen I, Aponte JJ, Segovia R, et al. Derivation and validation of guidelines for stool cultures for enteropathogenic bacteria other than <i>Clostridium difficile</i> in hospitalized adults. <i>J Am Med Assoc</i> 2001; 285: 313–319. García-Rodríguez JA, Martín Sánchez AM, Canut Blasco A, García Luis EJ, Luna Rodrigo G. Incidence of <i>Cryptosporidium</i> sp. in patients treated in a general hospital. Technics for the identification of oocysts in feces. <i>Med Clin (Barcelona)</i> 1989; 93: 164–168 [Article in Spanish].
10 Constitutional symptoms		
Unexplained fever	3%	Doherty JF, Grant AD, Bryceson AD. Fever as the presenting complaint of travellers returning from the tropics. <i>QJM</i> 1995;88: 277–281.
11 Mononucleosis	7%	Bottieau E, Clerinx J, Van den Eenden E, Van Esbroeck M, Colebunders R, Van Gompel A, et al. Infectious mononucleosis-like syndromes in febrile travelers returning from the tropics. <i>J Travel Med</i> 2006; 13: 191–197.
12 Laboratory indicators	Unknown	
13 Tumours		
Kaposi's sarcoma	45.4%*	Larocca L, Leto D, Celesta BM, Maccarone S, Mazza C, Cacopardo B, et al. Prevalence of antibodies to HHV-8 in the general population and in individuals at risk for sexually transmitted and blood-borne infections in Catania, Eastern Sicily. <i>Infez Med</i> 2005; 13: 79–85.

* Presence of human herpesvirus-8 antibodies.

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