



# 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



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## **List of abbreviations**

AIDS	acquired immunodeficiency syndrome
ART	antiretroviral treatment
DOTS	directly observed treatment, short course
HIV	human immunodeficiency virus
HTC	HIV testing and counselling
IDU	injecting drug user
MSM	men who have sex with men
MTCT	mother-to-child transmission
NGO	nongovernmental organization
NSP	needle and syringe programmes
OST	opioid substitution therapy
PITC	provider-initiated testing and counselling
PMTCT	prevention of mother-to-child transmission of HIV
STI	sexually transmitted infection
TB	tuberculosis
UNAIDS	United Nations Joint Programme on HIV/AIDS
UNODC	United Nations Office on Drugs and Crime
WHO	World Health Organization

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### **For more details and references**

This policy framework and its recommendations are based on a comprehensive review and analysis of the evidence and extensive consultations regarding HTC in the WHO European Region. For more details on each of the elements addressed in the framework and a complete list of references, see the accompanying background paper: *Increasing access to HIV testing and counselling as an essential component of efforts to achieve universal access to HIV prevention, treatment, care and support in the European Region of the World Health Organization.*

## Summary

In the WHO European Region, many people living with HIV are not aware of their serostatus. As a result, they may miss opportunities to access treatment, care and support in a timely fashion and may unknowingly transmit HIV. Member States therefore need to increase efforts to scale up access to and uptake of HIV testing and counselling services. This policy framework contains ten main principles and provides detailed recommendations to guide Member States as they endeavour to scale up HIV testing and counselling.

- Scaling up HIV testing and counselling is both a public health and human rights imperative and must be linked to broader efforts to achieve universal access to comprehensive, evidence-based HIV prevention, treatment, care and support (page 4).
- Expanded HIV testing and counselling must be tailored to different settings, populations and client needs (page 5).
- Efforts to increase access to and uptake of HIV testing and counselling should include implementation of provider-initiated testing and counselling in health facilities when appropriate (page 6).
- Efforts to increase access to and uptake of HIV testing and counselling must meet the needs of most-at-risk and vulnerable populations and expand beyond clinical settings and involve civil society and community-based organizations in providing the HIV testing and counselling services (page 8).
- Rapid HIV tests should be used where appropriate (page 9).
- Regardless of where and how HIV testing is done, it must always be voluntary and with the informed consent of the person being tested, adequate pre-test information or counselling, post-test counselling, protection of confidentiality and referral to services (page 10).
- HIV testing policies and practices should be reviewed to eliminate any non-voluntary forms of testing (page 12).
- Efforts to increase access to and uptake of HIV testing and counselling must be accompanied by equal efforts to ensure supportive social, policy and legal environments (page 12).
- In each country, consultations should be undertaken to formulate plans for expanded HIV testing and counselling based on this framework (page 13).
- Efforts to expand access to HIV testing and counselling must be carefully monitored and evaluated (page 14).

## Background

### **HIV continues to pose a major public health challenge in the WHO European Region.**

1.5 million people were estimated to be living with HIV in eastern Europe and central Asia in 2008, and 850 000 in western and central Europe (1). In 2008, 51 600 HIV cases were diagnosed and reported by 48 of the 53 countries in the Region<sup>1</sup> and Liechtenstein (2), more than double the number reported in 2000. The rate of HIV cases varied widely among the three geographical areas, at 179 reported cases per million population in the East, more than double that of the West (72/million) and more than ten times that of the Centre (15/million) (2).<sup>2</sup>

There are important differences in the dominant modes of HIV transmission in the WHO European Region, with a marked increase in diagnoses among men who have sex with men (MSM) in western Europe. MSM account for the largest number of new diagnoses in several countries of central and western Europe (2). Conversely, in eastern Europe, HIV predominantly affects male injecting drug users (IDUs), although the proportion of newly-infected women has increased markedly (3,4) and MSM are also heavily affected. In many countries in the Region, particularly in some migrant and ethnic minority communities in western Europe, HIV infection through heterosexual contact has risen.

Faced with a worsening HIV epidemic and the need to address public health and social challenges, in 2004 government representatives from Europe and central Asia adopted the Dublin Declaration on Partnership to Fight HIV/AIDS in Europe and Central Asia, in which they agreed to more effectively tackle the epidemic and its consequences (5). Globally, at the 2005 World Summit (6) and the United Nations General Assembly High-Level Meeting on HIV/AIDS in June 2006 (7), governments endorsed scaling up HIV prevention, treatment, care and support with the goal of coming as close as possible to universal access by 2010.

### **Why must access to and uptake of HIV testing and counselling (HTC) be increased?**

In an effort to reach the goal of universal access and successfully tackle HIV epidemic, increasing access to and the uptake of HTC and decreasing the number of people who are unaware of being infected remains one of the major challenges. It has been estimated that in the European Union around a third of those infected are not aware of their serostatus (8, 9), while in some countries in eastern Europe and central Asia, more than 60% of people with HIV remain undiagnosed (10). Lack of knowledge of HIV status is a key issue for both individuals and society. HTC can provide an opportunity for timely access to appropriate treatment, care and support; late presenters suffer greater morbidity and mortality than those diagnosed early.

HTC is also important for both primary and secondary HIV prevention. Quality HTC can help prevent HIV infection through counselling to discourage high-risk behaviour and support protective behaviour. People who learn that they are HIV-infected can take steps to decrease the

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<sup>1</sup> West (23 countries): Austria, Andorra, Belgium, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Israel, Italy, Luxembourg, Malta, Monaco, Netherlands, Norway, Portugal, San Marino, Spain, Sweden, Switzerland and the United Kingdom; Centre (15 countries): Albania, Bosnia and Herzegovina, Bulgaria, Croatia, Cyprus, Czech Republic, Hungary, Montenegro, Poland, Romania, Serbia, Slovakia, Slovenia, The former Yugoslav Republic of Macedonia and Turkey; East (15 countries): Armenia, Azerbaijan, Belarus, Estonia, Georgia, Kazakhstan, Kyrgyzstan, Latvia, Lithuania, Republic of Moldova, Russian Federation, Tajikistan, Turkmenistan, Ukraine and Uzbekistan.

<sup>2</sup> No data were available for Austria, Denmark, Liechtenstein, Monaco, Russian Federation or Turkey.

risk of transmitting HIV to injecting and sexual partners. The importance of this for HIV prevention is enhanced in settings where antiretroviral treatment (ART) is available and accessible to all who need it, given its value in reducing viral load and the amount of virus circulating in the community (11–13). Pregnant women who learn that they are HIV-positive can take steps to reduce HIV transmission to their babies.

Efforts to increase access to and uptake of HTC must address the factors that create barriers to it and take advantage of approaches that have proved to overcome them. In practice, this means moving towards evidence-based and rights-based HIV testing policy and practice, recognizing that respect and protection of human rights and ethical principles facilitates acceptance, implementation and success of HTC programmes and HIV prevention, treatment, care and support measures. On the other hand, approaches that erode human rights and ethics and create an environment of fear, intolerance and coercion undermine efforts to scale up HTC and public health interventions that aim to encourage disclosure and partner notification (14).

## **Scope and purpose**

The goal is to assist Member States in their efforts to scale up access to and uptake of high-quality HTC services that respect ethical principles and human rights, as a critical component of their efforts to reach universal access to comprehensive HIV prevention, treatment, care and support. Many countries in the WHO European Region have already started such efforts (15), but the high number of people who continue to be diagnosed late suggests that efforts to scale up HTC can be further improved.

Through an extensive consultation process, the WHO Regional Office for Europe developed this policy framework, based on evidence, international guidance and local and regional experience and expertise. It complements the *Guidance on provider-initiated HIV testing and counselling in health facilities* (16), which only addresses provider-initiated testing and counselling (PITC) in health facilities. In contrast, this policy framework addresses efforts to increase access to HTC both in and outside health facilities. Furthermore, it aims to respond to the particular needs and challenges in the WHO European Region, where the HIV epidemic is mostly concentrated among most-at-risk and vulnerable populations, particularly IDUs, MSM, some migrant and ethnic minority communities and prisoners and people in other closed settings.

## **Target audience**

The policy framework is intended for a wide audience, particularly policy-makers, national AIDS programme planners and coordinators, health-care providers and nongovernmental organizations (NGOs) involved in providing HIV-related services in the WHO European Region.

## Key principles and considerations

### **1. Scaling up HTC is a public health and human rights imperative and must be linked to broader efforts to achieve universal access to comprehensive, evidence-based HIV prevention, treatment, care and support.**

Scaling up voluntary, quality HTC is essential for an effective response to HIV, and is both a public health and a human rights imperative. However, efforts to scale up HTC in order to identify undiagnosed HIV-positive individuals are not enough.

HTC is never a goal in itself, but is motivated by HIV prevention and treatment, care, and support goals. Consequently, the efficacy of HTC policies and programmes is co-determined by the availability of comprehensive HIV prevention, treatment, care and support programmes. People who access HTC should always:

- have the benefit of treatment (including ART), care and support as needed;
- have access to comprehensive, evidence-based HIV prevention services that enable those testing negative to avoid infection and those testing positive to reduce the risk of transmission to their partners (or, if pregnant, to their babies), as well as the risk of being re-infected; and
- be protected from stigma, discrimination and violence through a supportive social and legal environment.

*The ultimate goal is not simply to increase access to and uptake of HTC, but to support HIV prevention and provide treatment (including ART), care and support to all who need it.*

All countries in the WHO European Region are committed to the goal of universal access. Nevertheless, in many countries access to evidence-based HIV prevention and/or treatment (including ART), care and support is far from universal. This compromises the right to health of people living with or at risk of HIV, and reduces the effectiveness of national responses. Significant progress in increasing access to ART has been achieved, but in many countries in the Region many of those who need ART do not have access to it. In some countries, interruptions in the supply of antiretroviral medications and intermittent availability of laboratory tests for HIV negatively affect patients' health, undermine confidence in health systems (17,18), and can lead to widespread development of HIV drug resistance. The lack of access to ART is particularly acute for marginalized populations (19). In some countries, people may be denied treatment if they are known to be using drugs (20). In others, access to treatment is made difficult by informal payments for diagnosis and treatment, or combining HIV treatment with other necessary treatment is not possible (18,21). Access to opioid substitution therapy (OST), an important component of strategies for retaining IDUs in ART programmes (22), remains very limited in many countries, particular in central and eastern Europe, and is not provided at all in some countries.

HTC can help prevent people from becoming infected with HIV, or help people living with HIV avoid transmitting the virus, by discouraging high-risk behaviour and reinforcing protective behaviour. However, in many countries and in many settings, essential HIV prevention measures are not provided. For example, in many countries in the Region with HIV epidemics fuelled by injecting drug use, access to needle and syringe programmes (NSP) and OST is limited by legal frameworks and prevailing attitudes (23). In most countries in the Region, prisoners have inadequate access to HIV prevention measures, although condom provision, OST and NSP have

been successfully introduced in some prison systems and proved to be effective at preventing the spread of HIV (24,25). Sex workers, migrants, ethnic minorities and MSM may also face barriers to accessing HIV prevention, either because services targeting them are insufficient or they avoid services due to widespread violence, stigma and discrimination.

Because HTC is motivated by HIV prevention and treatment, care and support goals, it should not be done without assured referral for all tested to HIV prevention, care and support and the earliest possible access to ART and other needed treatments.

## **2. Expanded HTC must be tailored to different settings, populations and client needs.**

Various models for offering HTC are currently used in the Region – some based on the primary care sector, some based on the secondary care sector and others operating through dedicated AIDS centres or with the support of NGOs – and few have been subjected to rigorous research of their effectiveness, efficiency or equity (26). The evidence needed to inform debates about the best way to implement HTC programmes therefore is incomplete (27), but shows that simply increasing the number of sites offering HTC is not enough to increase its uptake (19).

Studies that address testing barriers and facilitators have commonly identified the former on many levels (26,27–29). These include patient-related barriers, such as not recognizing that they are at risk, lacking information on testing possibilities, fear of the consequences (including legal) of positive testing and diagnosis (30–32). They also include health care/managerial/policy related barriers, such as:

- inability of general practitioners to pro-actively offer testing and to communicate its benefits due to time or technical restraints;
- failure by doctors to recognize symptoms;
- absence of clear national guidelines regarding HTC;
- lack of free access to quality HTC;
- failure to target most-at-risk and vulnerable populations and/or to expand service models and/or provide links to known services (30);
- criminal laws and law enforcement practices that can drive people with or at risk of HIV underground, prevent evidence-based interventions, and reduce public support for action (33);
- failure to provide conveniently located services (27,34); and
- shortage of trained counselling staff.

Cultural, linguistic or socioeconomic barriers to the health care system may compound the problem, particularly for marginalized populations. People are more likely to actively seek HTC when they perceive benefits of testing. The decision to test may ultimately reflect an assessment of whether knowing and being known as HIV-positive is advantageous (35), especially in settings characterized by poor health care and ART access and high stigmatization of most-at-risk and vulnerable populations and/or people who are HIV-positive. Ultimately, “it is not so much the changing medical aspects of HIV that shape contemporary testing decisions, but the social meaning and social consequence of HIV diagnoses.” (29,36–38).

On the other side, there is evidence of what can be done to facilitate access to and uptake of HTC, and to maximize the benefits of HTC, including:

- improving the quality of HTC services (39,40);
- expanding alternatives to traditional on-site, clinical HIV-antibody testing of venous blood, particularly for at-risk and vulnerable populations (28);

- improving links and access to evidence-based HIV prevention, treatment, care and support, and making the social, legal and policy environments more supportive (28);
- using rapid tests and providing tests in locations and conditions convenient to clients (27);
- introducing PITC in prenatal care (41,42);
- introducing PITC in certain other health-care settings, such as sexually transmitted infection (STI) clinics and facilities providing tuberculosis (TB) services, which has been found to be acceptable to patients and led to increased uptake of testing (43–45); and
- using targeted media campaigns to encourage uptake of HIV testing (27).

Member States are advised to expand models of HTC service delivery and to ensure that their efforts to increase access to and uptake of HTC are tailored to different settings, populations, and client needs.

### **3. Efforts to increase access to and uptake of HTC should include implementation of PITC for symptomatic patients and those with suspected primary HIV infection, and in selected health facilities.**

In 2007, WHO and the United Nations Joint Programme on HIV/AIDS (UNAIDS) released guidance on PITC in health facilities (16), recommending implementation of PITC, under certain conditions, in health care settings in countries with generalized HIV epidemics, as well as in some health care settings in countries with low-level or concentrated epidemics. According to the guidance, PITC refers to HTC recommended by health care providers to people attending health care facilities. The guidance emphasizes that PITC is voluntary and must always include informed consent to the test, as well as counselling and effective process to ensure that the individual's HIV status remains confidential (16) (see also Principle 6 below).

Many opportunities for diagnosis and counselling at health facilities are missed when systems rely primarily on individuals to initiate HTC. PITC can help ensure earlier diagnosis and access to HIV-related services. Implementing it under certain circumstances and in some health care settings is therefore essential in all countries in the WHO European Region. At the same time, throughout the Region, where HIV is mainly concentrated among key populations at risk, widespread use of PITC in all health-care settings is not appropriate. Most people will have a low risk of exposure to HIV and recommending HTC to all persons attending all health care facilities may not be feasible, necessary or appropriate (15,16,46).

#### ***3.1 PITC for symptomatic patients and those with suspected primary HIV infection should be prioritized.***

HTC should be recommended to all adults, adolescents and children presenting at health facilities with signs and symptoms suggestive of underlying HIV infection, including TB,<sup>3</sup> and to children known to have been perinatally exposed to HIV. Failure to recommend HTC to a patient with potentially HIV-related symptoms is substandard medical practice.

In addition, HTC should also be recommended to anyone presenting at health facilities with symptoms of primary HIV infection or seroconversion illness. This may be the only clinical opportunity to detect HIV before advanced immunosuppression years later and also represents a unique opportunity to prevent onward transmission, as an individual is considerably more infectious at this stage. Implementation will require a major effort to educate health-care providers about the typical features of primary HIV infection and the benefits of discussing HIV risk and recommending HTC to people presenting with these symptoms. Health-care providers

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<sup>3</sup> For a list of clinical indicator diseases for adult and paediatric HIV infection, see (15):7–8.

also need to be aware of the limitations of available HIV tests (15) and if necessary urgently refer patients to specialist services and recommend retesting (15,47).

### ***3.2 Consideration should be given to implementing PITC in selected health facilities.***

Countries should consider implementing PITC in the following health facilities or services. Decisions about whether to implement PITC in some or all of these facilities and, if so, how this should be done, should be guided by an assessment of the epidemiological and social context.

#### *Facilities providing STI services*

In most countries in the Region, a large (and sometimes growing) proportion of HIV is transmitted through sexual activity. The presence of an STI can increase the risk of HIV acquisition or transmission. STI settings are important venues for increasing knowledge of HIV status among sexually active men and women and access to HIV prevention, care, treatment and support (48).

#### *Facilities providing TB services*

In some countries, a significant percentage of all TB cases are co-infected with HIV (49), in which case TB services facilities can be important for increasing knowledge of HIV status and providing a critical entry point for HIV prevention, treatment, care and support.

#### *Services for most-at-risk and vulnerable populations*

Because of their special health needs, populations most at-risk for HIV may be more likely to attend services such as acute care or drug dependence treatment. Therefore, countries should consider adopting policies to offer HTC to all patients attending those facilities or services, if epidemiologically appropriate and socially acceptable. Plans for PITC in such settings should prioritize implementation of a supportive social, policy and legal framework.

In many countries, people who inject drugs, sex workers, migrants and mobile populations are more susceptible to coercion, discrimination, violence, abandonment, incarceration or other negative consequences upon disclosure of an HIV-positive test result. In some countries, MSM are also more susceptible to discrimination and violence. Before PITC can be introduced in services for these populations, special training and supervision for health care providers to uphold standards of informed consent and confidentiality is required. These populations may also require more information than others to make informed decisions about taking an HIV test. When offering the testing, health care personnel need to emphasize the voluntary nature of the HIV test, the right to decline it and that declining a test will not affect access to services. Additional discussion of the benefits and risks of HIV testing and disclosure and social support referral needs will also usually be required. Where there is a power imbalance leading patients to feel apprehensive of declining an offer or recommendation of HTC made by a provider, particular efforts are needed to ensure that testing is truly voluntary. Countries should consider requiring that patients in these settings must specifically agree to the HIV test – rather than allow an approach under which patients are tested unless they specifically decline the offer or recommendation of testing.<sup>4</sup>

Involving representatives and advocates of the populations in the development of HTC protocols and monitoring and evaluation of PITC programmes is essential to ensure that the most appropriate and acceptable practices are followed.

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<sup>4</sup> As suggested by WHO/UNAIDS (16 p.25).

Finally, health services should ensure that mechanisms are in place for referral to prevention, treatment, care and support services provided by community-based organizations and civil society groups.

#### *Antenatal, childbirth and postpartum services*

There are clear advantages in determining the HIV status of pregnant women before delivery, with the risk of transmission of the virus nearly eliminated implementing the evidence-based interventions (50). Thus, some countries have implemented PITC for all pregnant women, while others routinely offer HIV testing only to those women thought to be at high risk of HIV exposure (51) or specifically requesting it. Particularly the latter option results in much lower uptake than when PITC is implemented (52–54). Some have therefore suggested that it is time to adopt PITC in all antenatal clinics across Europe, but there may be areas where the HIV prevalence is so low that this strategy would not be cost-effective.

It is recommended that all countries in the region adopt a comprehensive approach to prevention of mother-to-child transmission of HIV (PMTCT), including:

- 1) preventing HIV infection among women of child-bearing age and their partners
- 2) preventing unintended pregnancies among HIV-infected women
- 3) preventing HIV transmission from infected women to their babies
- 4) providing care and support to HIV-infected women, their infants and families.<sup>5</sup>

Decisions about whether to make PITC part of such services need to be based on an assessment of local resources and the epidemiological and social context. Many countries will have the resources to implement PITC as part of a broader PMTCT plan whereas in others it may be necessary to scale up other elements of the comprehensive PMTCT plan before it is possible to adopt a policy of PITC for all pregnant women. In particular, measures need to be in place to ensure that PITC leads not only to increased uptake of HTC, but also of the interventions reducing the risk of MTCT and benefiting HIV-positive mothers, including ART.

## **4. Efforts to increase access to and uptake of HTC must meet the needs of most-at-risk and vulnerable populations and expand beyond health care settings.**

### ***4.1 Meeting the needs of most-at-risk and vulnerable populations***

Increasing and improving access to HTC is particularly important for the populations that are most at risk and most vulnerable including IDUs, MSM, sex workers, migrants and mobile populations and ethnic and national minorities. Many in these traditionally underserved and socially marginalized communities rarely use the health system and require other sources of safe, voluntary and accessible HTC, offered or recommended to them in a peer-driven and non-judgmental manner. Examples include services by mobile clinics (55), community settings or other outreach, for example by empowering non-governmental, community-based organizations to provide HIV tests to their peers “where they are” (34,56). For people who use drugs, HTC may be offered or recommended at needle and syringe programmes and other harm-reduction services, drop-in centres or outreach programmes (57,58).

Establishing such services acknowledges that many individuals may prefer to test in non-medical settings or may not be registered with primary care. Studies have shown that such services are acceptable and feasible and may encourage potentially high-risk and vulnerable individuals who would not otherwise have accessed HIV testing through conventional services (59). Therefore,

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<sup>5</sup> As recommended by the European Strategic Framework for the Prevention of HIV Infection in Infants, developed by UNAIDS cosponsors under the leadership of WHO in 2004.

developing them as a complement to expanding health-care-based services should be encouraged. In some countries, this may require changes to laws and policies, including allowing non-health-care professionals, including those in NGOs, to offer or recommend and perform HTC. Development of the services should be accompanied by social mobilization and education initiatives to encourage people belonging to most-at-risk and vulnerable populations to learn their HIV status and access services.

#### ***4.2 Meeting the needs of prisoners, detainees and people in other closed settings***

Efforts to increase access to and uptake of HTC should also include prisoners, detainees, and people subjected to compulsory forms of drug treatment, with special considerations. In recognition that prisons, other places of detention and compulsory drug treatment centres are not health care settings to which the 2007 WHO/UNAIDS *Guidance on provider-initiated HIV testing and counselling in health facilities* would apply, appropriate guidance has been developed for prisoners, detainees and people undergoing compulsory drug treatment (60,61). Consistent with this guidance, countries in the WHO European Region should ensure that all people in these settings have easy access to HTC programmes, at any time during their stay. They should be informed about the availability of services, both at the time of their admission and regularly thereafter. In addition, health-care providers in these settings should offer HTC to all during medical examinations and recommend HTC in the event of signs, symptoms or medical conditions that could indicate HIV infection, including TB, to assure appropriate diagnosis and access to necessary HIV treatment, care and support as indicated.

In all cases, all forms of coercion must be avoided and voluntary, informed consent must be provided. Efforts to scale up access to HTC in these settings, as in the general community, should not be undertaken in isolation, but should be part of a comprehensive HIV programme aimed at improving health care and at achieving universal access to HIV prevention, treatment, care and support for prisoners. This should include providing access to condoms, sterile injection equipment, OST and other evidence-based drug dependence treatment, interventions to prevent mother-to-child transmission for pregnant women and uninterrupted provision of ART for those living with HIV. Any policies and practices in these settings that discriminate against people living with HIV should be reviewed and changed, recognizing that increasing access to HTC must go hand in hand with greater protection from HIV-related discrimination and violence. In particular, policies that provide for segregation of the HIV-positive in these settings or their exclusion from any programmes or activities should be repealed.

### **5. Rapid HIV tests should be used, where appropriate, to support efforts to increase access to and uptake of HTC.**

The introduction of sensitive, specific, simple-to-use, rapid HIV tests (also called point-of-care tests) that do not require sophisticated laboratory services is an important advance. Such tests are increasingly used, including in outreach services. Their advantages – particularly for facilities where laboratory services are weak, community-based HTC settings or outreach – include visibility and quick turn-around. Testing can occur outside laboratory settings and in non-medical settings, does not require specialized equipment and can be carried out in clinical and non-clinical facilities by appropriately trained personnel, including counsellors. However, trained laboratory supervisors are required for supervision, quality assurance, including quality control and bio-safety. NGOs and community-based organizations should also be trained to perform rapid HIV tests. Tests should be of assured quality. Decisions on whether to use HIV rapid tests or traditional assays should take into account all advantages and disadvantages,

including cost and availability of the test kits, reagents and equipment, staff, resources, infrastructure, laboratory expertise and personnel, as well as considerations such as the number of samples to be tested, sample collection and transport methods, the testing setting, convenience and the testee's ability to return for results.<sup>6</sup>

## **6. HIV testing must always be done with informed consent, adequate pre-test information or counselling, post-test counselling, protection of confidentiality and referral to services.**

In the early years of the HIV epidemic, aggressive calls for punitive, forcible testing sparked widespread concern about the effects of such strategies on individual rights and the spread of the epidemic. Eventually, members of affected communities and public health professionals recognized that HIV testing must be voluntary and that informed choice is central to creating a climate of confidence and trust between the person being tested and the service providers. Three principles of HIV testing (the “three Cs”) were established as norms:

- counselling and information about HIV/AIDS before and after the test;
- consent to be tested given in an informed, specific and voluntary way by the person to be tested; and
- confidentiality of test results and of the fact of seeking a test.

Beyond these components of the testing process itself, governments are also responsible for ensuring that HIV testing, like all other essential health services, is not offered, recommended or provided in a way that discriminates against any person or group of people (62). In addition, the right to be free from discrimination and the right to security of person require that governments take into account potential outcomes of HIV testing – including stigma, discrimination, violence and other abuse – in policy and practice. Governments must do all they can to prevent such human rights violations, both for the protection of the individual and the effectiveness of the national response to HIV.

### ***6.1. Informed consent and pre-test information or counselling***

In some settings providing pre-test information – rather than more extensive pre-test counselling (including HIV prevention counselling) – may be justified in order to make pro-actively offering HTC feasible. Human rights and public health do not require cumbersome procedures for pre-test counselling or that informed consent be recorded in writing, but they do require that people be given adequate information on which to base informed and truly voluntary consent to HIV testing, whether it is provider or client-initiated.

As efforts to increase access to and uptake of HTC are undertaken, pre-test counselling, including prevention counselling, may remain important and feasible in certain circumstances. However, it is inevitable that making the offer of testing a widespread routine will entail the involvement of providers without either the time and/or the expertise for pre-test counselling, all the more so where PITC is implemented. In such cases, provision of pre-test information, coupled with giving clients an opportunity to ask questions, is all that is required. As part of this, testing providers must provide the client with information explaining the following:

- the reason(s) for testing
- its clinical benefits and risks (discrimination, abandonment, etc.)

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<sup>6</sup> See the WHO diagnostics website for further information: <http://www.who.int/hiv/amds/diagnostics/en/index.html>.

- the services available in case of negative or positive results (including the availability of ART)
- that the result will be treated confidentially and shared only with involved care providers.

Providers must also inform clients that they have the right to decline the test, that declining an HIV test will not affect their access to other services and that if the test result is positive, disclosure to contacts who may be at risk will be encouraged.

An opportunity should always be provided for people to ask questions, and they must be given enough time to make a decision about consenting to the test. They should also be made aware of any laws mandating disclosure of HIV status to sexual and/or drug-injecting partners, contact tracing or criminalizing HIV transmission.

Verbal consent by the individual being tested is normally adequate. Institutions or jurisdictions that require consent for testing to be given in writing are encouraged to review their policy.

Clear legal regulations and policies should stipulate the age and/or circumstances in which minors may consent to HIV testing, and how the assent of and consent for adolescents should best be assessed and obtained. Sufficiently mature adolescents should be permitted to give their own informed consent to HIV testing.

### ***6.2 Post-test counselling***

Post-test counselling must always be an integral component of the HIV testing process. Everyone undergoing HIV testing must be counselled when their test results are given, regardless of the result.

### ***6.3 Ensuring confidentiality, privacy and security of data***

Confidentiality is an ethical principle particularly relevant to health care. People will only share information that may be critical to decisions about effective clinical care and treatment if they feel sure that it will remain confidential.

Privacy must also be ensured. For example, informed consent should be sought and given in a private setting and post-test counselling for HIV-positive clients and other communications relating to HIV status should take place away from clients or staff not involved in the case at hand.

Member States should have nationally approved privacy, confidentiality and security definitions, guiding principles and recommendations for HIV-related data, with relevant capacities for their maintenance. Privacy and confidentiality laws should be in place and be reviewed and known by everyone accessing health data.

### ***6.4. Ensuring referral to services***

HIV test results must be communicated to the person tested with an explanation of the available prevention, treatment (including ART), care and support services. Programmes for other chronic illnesses, sexual and reproductive health and community-based HIV prevention, treatment, care and support are especially important resources and it is important to maintain collaboration with them. At minimum, referral should include information about whom to contact as well as where, when and how to obtain the services required.

## **7. Testing policies and practices should be reviewed to eliminate any non-voluntary forms of HIV testing.**

In some countries in the Region, HIV testing is required by legislation or policy for certain people, in certain situations. In other cases, it is officially voluntary, according to the law, regulation or policy, but people are more or less subtly coerced into it. Mandatory or compulsory testing continues being a reality, particularly for members of most-at-risk and vulnerable populations. Sometimes it is done without the knowledge of the person being tested. The purpose of such testing is not to provide access to HIV prevention, treatment, care and support, but most often to exclude people with HIV from access to certain services, or otherwise impose restrictions on them. Such mandatory or compulsory forms of testing violate ethical principles and basic rights of consent, privacy and bodily integrity; they cannot be justified on public health grounds.

As countries expand the availability and accessibility of HTC, including by implementing PITC, in some settings and some circumstances offering (and recommending) HTC should not be confused with allowing testing without informed consent; testing must always be voluntary (16). Therefore, Member States are advised to review their HIV testing policies and practices to eliminate any laws, policies and regulations requiring mandatory or compulsory HIV testing and ensure that any such practices cease and that clients tested without their consent have appropriate recourse. The only exception is HIV screening for blood, blood products and before all procedures involving transfer of bodily fluids or body parts, such as artificial insemination, corneal grafts and organ transplant, as recommended by UNAIDS/WHO (63).

## **8. Efforts to increase access to and uptake of HTC must be accompanied by equal efforts to ensure supportive social, policy and legal frameworks to maximize benefit and minimize harm to those tested.**

At the same time as efforts to increase access to, and uptake of, HTC are undertaken, equal efforts must be made to ensure that a supportive social, policy and legal framework is in place to maximize positive outcomes and minimize potential harms to people testing for HIV. If the following elements are not in place, efforts to increase access to quality HTC are unlikely to succeed. Countries need to assess their situation in terms of these elements and address any problems as they plan for expanded HTC:

### *Community preparedness and social mobilization*

Public information campaigns should be conducted to raise awareness about HIV, promote the rights of those living with HIV and most-at-risk populations and the benefits of knowing and disclosing one's HIV status, and provide information about available services.

### *Adequate resources and infrastructure*

Policy-makers and planners should anticipate the additional resources required for implementation of expanded HTC, including training, purchasing commodities and adequate clinical infrastructure. Additional resources may be needed to assist non-governmental, community-based organizations to offer HTC and/or provide follow-up services.

It is crucial that countries recognize that if HTC scaling-up is to reach its objectives, new and additional financial resources will have to be found, not only for expanded HTC, but also for the conditions that will make it successful – in particular, scaled up HIV prevention, treatment (including ART), care and support and human rights interventions.

Expanding access to HTC will require major investment in human resources, that is, training and ongoing supervision of providers and administrators of HTC programmes. People living with HIV, AIDS service organizations and other community-based organizations can be important sources of skilled lay personnel for service delivery, follow-up, referrals, monitoring and evaluation. In some settings, expanding the types of providers authorized to carry out HTC may require amending laws and regulations.

*Codes of conduct for testing providers and methods of redress for clients*

Facilities providing HTC should have codes of conduct for providers and methods of redress for patients whose rights are infringed. Appointment of an independent ombudsman or patient advocate to whom breaches of protocol and codes of conduct can be reported should be considered.

Efforts to increase HTC must also go hand-in-hand with efforts to ensure that supportive social, legal and policy environments are in place. This includes providing real protection – in practice, and not just on paper – from HIV-related discrimination and abuse for people living with HIV and members of most-at-risk and vulnerable populations. Countries need to review the use of criminal laws and prosecutions against conduct carrying the risk of HIV transmission to ensure that overbroad application of criminal sanctions does not undermine efforts to increase access to and uptake of quality HTC, or HIV prevention, treatment, care and support services.

Other important components of a supportive social, legal and policy environment, such as ethical partner notification policies and procedures, should also be in place in every country. They may not always be in place before efforts to increase access to HTC are undertaken, but they should be addressed as part of national plans to scale up HTC and achieve universal access to HIV prevention, treatment, care and support. Optimal delivery of expanded HTC requires removal of regulatory barriers and the presence of enforced and monitored supportive laws and policies. Implementing these broad social and legal measures is the responsibility of diverse stakeholders, including parliamentarians, ministries of the interior, health and justice and civil society groups, emphasizing the need for multisectoral commitment to scaling up expanded HTC.

## **9. Consultations should be undertaken to formulate plans for expanded HTC.**

This policy framework offers guidance for policy-making and practice in countries across the WHO European Region. However, decisions on how best to increase access to and uptake of HTC will depend on assessments in the particular countries, which need to include local epidemiology, infrastructure and financial and human resources; the available HIV prevention, treatment, care and support services and programmes; and the social, policy and legal frameworks for protection against the adverse consequences of HIV testing, such as discrimination and violence.

Implementation decisions should be made in consultation with all relevant stakeholders, including civil society groups, people living with HIV and representatives of most-at-risk and vulnerable populations. Involving targeted individuals and communities in the development, policy formulation, planning, implementation, monitoring and evaluation of HTC is essential. Lay perceptions of risks, costs and benefits associated with HIV testing may differ substantially from the perspective of medical experts, and effective policies and programmes must therefore adequately represent the perspective of targeted individuals.

Some countries face substantial human and financial constraints to implementing large-scale health service activities. It may be necessary to prioritize particular activities for the expansion of HTC, depending on the local context and resources. As such decisions are made, human rights

and ethical principles need to be taken into account, and the needs of populations most at risk and most vulnerable should be prioritized. Plans for expanding HTC should be part of or at least coordinated with, broader plans to reach universal access to HIV prevention, treatment, care and support.

## **10. HTC must be carefully monitored and evaluated.**

Beyond setting targets for scaled-up HTC and documenting the number of people being tested,<sup>7</sup> efforts to increase access to and uptake of HTC will have to be carefully monitored and evaluated to ensure that, in practice people:

- have unproblematic access to free or affordable, high-quality HTC;
- are not coerced into testing, but give informed, voluntary consent;
- are diagnosed earlier;
- are referred and obtain access to needed services, particularly ART for those testing HIV-positive; and
- do not suffer exclusion or any other negative consequences.

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<sup>7</sup> For a set of indicators and benchmarks to be used to set programme objectives, and monitor and evaluate HIV interventions for IDUs, including HTC, see: WHO, UNODC, UNAIDS. *Technical guide for countries to set targets for universal access to HIV prevention, treatment and care for injecting drug users*. Geneva, 2009.

## Recommendations

- 1. Scaling up HTC is a public health and human rights imperative and must be linked to broader efforts to achieve universal access to comprehensive, evidence-based HIV prevention, treatment, care and support.**
  - 1.1 Member States should take action and make a long-term, sustainable national commitment to increase access to and uptake of high-quality HTC.
  - 1.2 Member States should coordinate their efforts to increase access to and uptake of HTC and integrate them into broader national plans to achieve universal access to comprehensive and evidence-based HIV prevention, treatment including ART, care and support.
  - 1.3 In particular, as access to HTC is increased, Member States with insufficient or inequitable access to ART must scale up efforts to improve access to ART, within the framework of a national universal access plan. Particular efforts are needed to ensure equitable access for members of most-at-risk and vulnerable populations. As part of these efforts, Member States with no or limited access to OST must make immediate plans to introduce it or to scale it up.
  - 1.4 Member States should build referral, patient-tracking and follow-up mechanisms into HTC programmes, to ensure tested patients receive HIV prevention, treatment, care and support.
  
- 2. Efforts to increase access to and uptake of HTC must be tailored to different settings, populations and client needs.**
  - 2.1 Member States should expand models of HTC service delivery and ensure that their efforts to increase access to and uptake of HTC are tailored to different settings, populations, and client needs.
  
- 3. Efforts to increase access to and uptake of HTC should include implementation of PITC for symptomatic patients and those with suspected primary HIV infection, and in selected health facilities.**
  - 3.1 Member States should adopt policies whereby HTC is recommended to all adults, adolescents and children who present to health facilities with signs and symptoms suggestive of underlying HIV infection, including TB; and to children known to have been perinatally exposed to HIV.
  - 3.2 HTC should also be recommended to anyone presenting at a health facility with symptoms of primary HIV infection or seroconversion illness. This requires a major effort to educate health-care providers about the features of primary HIV infection.
  - 3.3 Member States should consider implementing PITC in facilities providing services for STIs, TB, most-at-risk and vulnerable populations and antenatal, childbirth and postpartum services. Decisions should be made based on the local epidemiology, the availability of and access to comprehensive, evidence-based HIV-related prevention and treatment (including ART), care and support to all who need it, and the presence of supportive social, policy and legal environments to maximize positive outcomes and minimize potential harm to patients.
  
- 4. Efforts to increase access to and uptake of HTC must meet the needs of the most-at-risk and vulnerable populations in which the epidemic is concentrated, and expand beyond clinical settings.**
  - 4.1 Since many people belonging to most-at-risk and vulnerable populations do not access traditional health-care settings, Member States should implement innovative approaches such

as services delivered through mobile clinics, in community settings or through other types of outreach.

- 4.2 Efforts should include social mobilization and education initiatives to encourage people belonging to these groups to learn their HIV status and to access services.
- 4.3 Any legal or policy barriers to implementation of innovative approaches and involvement of civil society and community-based organizations in providing HTC services should be removed.
- 4.4 Efforts to increase access to and uptake of HTC must include prisoners, detainees and people subjected to compulsory forms of drug treatment, with special considerations. Member States should see that these groups have easy access to HTC services. In addition, health-care providers in these settings should pro-actively offer HTC to all during medical examinations and recommend it to those showing signs, symptoms or medical conditions that could indicate HIV infection, including TB. In all cases, all forms of coercion must be avoided and people must provide informed, voluntary consent. Efforts to increase access to HTC should not be undertaken in isolation, but as part of comprehensive HIV programmes aimed at improving health care, decreasing stigma and discrimination, protecting confidentiality of medical information and vastly scaling up access to comprehensive HIV prevention, treatment, care and support.

**5. Rapid HIV tests should be used, where appropriate, to support efforts to increase access to and uptake of HTC.**

**6. HIV testing must always be done with informed consent, adequate pre-test information or counselling, post-test counselling, protection of confidentiality and referral to services.**

- 6.1 Member States should ensure that providers receive training and education in delivering high-quality HTC programmes, based on protocols addressing the following key areas: ensuring an ethical process for obtaining informed consent, providing appropriate pre-test counselling/information, protecting confidentiality and privacy, avoiding stigma and discrimination, ensuring appropriate post-test counselling and referral.
- 6.2 Member States should implement clear legal and policy frameworks stipulating the age and/or circumstances in which minors may consent to HIV testing – allowing sufficiently mature adolescents to give their own informed consent – and how the assent of and consent for adolescents should best be assessed and obtained.
- 6.3 Member States should have nationally approved definitions, guiding principles, recommendations and related capacities for the maintenance of privacy, confidentiality and security in working with HIV-related data. Privacy and confidentiality laws should be in place and their relevant parameters must be reviewed and known by all those accessing health data. All relevant stakeholders, including people living with and affected by HIV, health care professionals, legal and ethical experts, civil society representatives and other stakeholders as appropriate, should be involved when laws and procedures related to HIV information are developed or reviewed.

**7. HIV testing policies and practices should be reviewed to eliminate non-voluntary forms of HIV testing.**

- 7.1 Member States should review, and change as necessary, their laws, regulations, policies and practices to eliminate any forms of non-voluntary HIV testing, with the exception of HIV screening for blood, blood products and before all procedures involving transfer of bodily fluids or body parts.
- 7.2 Instead, Member States should adopt legislation and policy providing for expanded access to free, voluntary and confidential HTC. These should empower appropriate

authorities to investigate complaints related to mandatory or compulsory HIV testing and prosecute those involved in testing for HIV without informed consent.

## **8. Efforts to increase access to and uptake of HTC must be accompanied by equal efforts to ensure supportive social, policy and legal environments.**

- 8.1 At the same time as they undertake efforts to increase access to, and uptake of, HTC, Member States must make equal efforts to ensure that a supportive social, policy and legal framework is created to maximize positive outcomes and minimize potential harms to people tested for HIV.
- 8.2 Member States should assess their community preparedness, social mobilization, resources, infrastructure and health-worker capacity to increase access to HTC with informed consent, confidentiality and counselling. They should take adequate steps to address any problems as HTC services are expanded. In particular, adequate resources must be made available for all components necessary to ensure that access to HTC is implemented in ways that maximise public health benefits while respecting and protecting human rights.
- 8.3 Member States should review policies, laws and regulations and amend them as necessary in order to allow task-shifting in health facilities and adequately trained lay personnel to carry out HTC, monitoring and evaluation.
- 8.4 Member States should ensure that codes of professional responsibility adequately protect patient confidentiality and provide recourse to any who have their confidentiality breached.
- 8.5 Member States should cost, budget and implement national programmes to secure legal and human rights protections for people living with, affected by or most at risk of HIV. These programmes should include: (a) legal audits and reforms of laws, policies and practices that create barriers to HTC and comprehensive HIV prevention and treatment, care and support; (b) adoption of legislation barring discrimination on the basis of disability and perceived disability, including drug dependency and HIV-positive status; (c) legal support services for people living with HIV and those most at risk of and vulnerable to HIV; (d) know-your-rights campaigns; (e) campaigns against stigma and discrimination; (f) training of health-care workers focusing on informed consent, confidentiality, non-discrimination and the duty to treat; and (g) training and sensitization of law enforcement agents, judges and lawyers on HIV and human rights, particularly in terms of supporting access to services, non-discrimination, non-violence, and freedom from harassment and arbitrary arrest and detention.
- 8.6 Member States should repeal any HIV-specific criminal laws. They should apply general criminal law only to the intentional transmission of HIV and audit its application to ensure it is not used inappropriately. They should redirect legislative reform and law enforcement towards addressing discrimination and other human rights violations against people living with HIV and people most at risk of exposure to HIV infection.
- 8.7 Member States should devote particular efforts towards creating social, policy and legal environments that support migrant and mobile population access to and uptake of HTC and HIV prevention, treatment, care and support.
- 8.8 Member States should develop national policies and codes of ethics to authorize ethical partner notification, but only in clearly defined circumstances.

## **9. National plans for expanded HTC should benefit from national and local consultations and from the input of all relevant stakeholders.**

In each Member State, plans for expanded HTC should be developed and implemented in consultation with all relevant stakeholders, including civil society groups, people living with HIV and representatives of most-at-risk and vulnerable populations. The plans should be informed by the principles in this policy framework, and by an assessment of the country's situation, including the local epidemiology, infrastructure, financial and human resources,

available HIV prevention, treatment, care and support services and programmes and the social, policy and legal frameworks for protection against adverse consequences of HIV testing, such as discrimination and violence.

**10. HTC must be carefully monitored and evaluated.**

Member States should ensure that monitoring and evaluation form an essential part of efforts to scale up access to HTC.

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