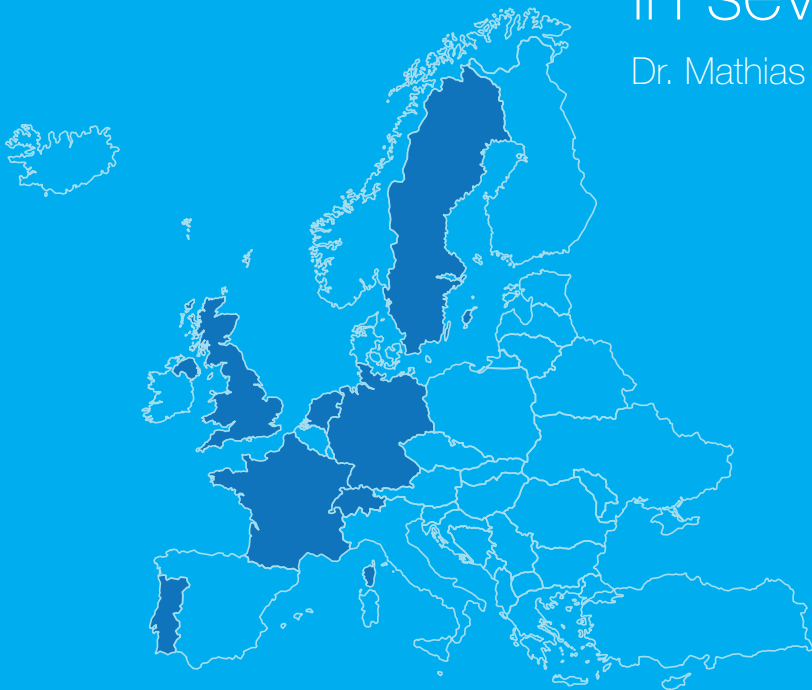

Comparative study of national HIV-testing strategies in seven European Countries

Dr. Mathias Bernhard Bonk



Bern, April 2018

Mandated by the Swiss Federal Office of Public Health (FOPH)
Division of International Affairs

PREFACE

Dear Reader,

The good news is that HIV infection has become a manageable chronic condition. Thanks to the increasing availability of antiretroviral therapy, millions of patients can now live a long and healthy life. However, despite the many success stories in this field, HIV incidence rates have been static or rising in recent years, especially in some European countries. This could be attributed to an increase in risk-taking behaviour, lack of political engagement in risk reduction, an increase in persons coming from high-prevalence countries or to late HIV diagnosis, all of which may lead to new infections.

According to UNAIDS estimations only 69% of the 36.7 million people worldwide living with HIV were aware of their infection in 2016. The European Center for Disease Prevention and Control estimated that in their region 1 out of 6 HIV positive individuals were unaware of their infection during this period. Of newly diagnosed patients, 51% had been diagnosed late and 30% were diagnosed with an advanced stage of the infection. The average time between HIV infection and diagnosis has increased to about three years, corresponding to a long period of missed opportunities for access to treatment and care, as well as the prevention of onward transmission of the virus. Therefore there is a need to increase efforts to scale-up testing approaches.

Ensuring access to testing and treatment was emphasized in the declaration on HIV and AIDS, adopted by the UN Member States during the General Assembly High Level Meeting in June 2016 (On the Fast-Track to Accelerate the Fight against HIV and to End the AIDS Epidemic by 2030). Switzerland supported the adoption of this declaration as well as the adoption of WHO's Global Health Sector Strategy on HIV 2016-2021 at the 69th World Health Assembly in Geneva in May 2016. This strategy highlights the need for renewed political commitment, additional resources and technical and programmatic innovations, including new HIV testing approaches.

To reach the UN "90-90-90" targets more evidence on the successes or failures of HIV testing measures needs to be collected and analysed.

Switzerland hopes to contribute to the achievement of these UN targets by sharing this comparative study. In the spirit of fostering the exchange of experiences, good practice and innovative models, we are confident that this tool will contribute to initiating national processes to ensure that most people living with HIV become aware of their infection and receive the treatment and care they need.

The discussions gained momentum also in Switzerland: As the present study is being completed, decisive steps are under way that could very soon legalise self-testing as an additional testing option. We hope you will find this document useful in our common endeavour to end the HIV / AIDS epidemic by 2030.

Tania Dussey-Cavassini

Former Swiss Ambassador for Global Health & Vice-Director General of the Federal Office of Public Health (2013-2017)

EXECUTIVE SUMMARY

The increasing availability of antiretroviral therapy has transformed HIV infection into a manageable chronic condition for millions of people worldwide, enabling them to live longer and healthier lives. Levels of HIV incidence have been stagnating in many countries and a substantial proportion of new infections occur during the acute and early infection of the partner. New and improved testing approaches are essential in order to reach millions of people with an undiagnosed HIV infection to ensure they receive the treatment and care they need and to protect their partners and contacts.

The Joint United Nations Programme on HIV/AIDS (UNAIDS) estimates that only 54% of the 36.9 million people worldwide living with HIV are aware of their serostatus. Therefore considerable efforts have been made to expand HIV testing services to achieve earlier diagnosis and treatment for the individual and to prevent the spread of the infection to those at risk, which is the essential basis for reaching the United Nations “90-90-90” targets (UNAIDS, 2015a).

The United Nations “90-90-90” targets aim at

- by 2020, 90% of all people living with HIV will know their HIV status
 - by 2020, 90% of all people diagnosed will have received sustained antiretroviral therapy (ART)
 - by 2020, 90% of all people on ART will have viral suppression.
- (UNAIDS, 2014a)

The aim of this study is to provide information about the current HIV / AIDS epidemiology, present international declarations and strategies as well as the most relevant international and national guidelines on HIV-testing. Furthermore this study is focusing on national HIV-testing policies and strategies from 7 European countries with a comparable HIV situation, including the suitability, efficacy and efficiency of these policies. In addition specific aspects like community-based testing, self-testing, the length of the window period, partner notification or multi-disease testing are described and good practice examples from selected and additional countries presented.

The study demonstrates the complexity of challenges, the diversity of stakeholders involved and the variety of measures and initiatives in the area of HIV counselling and testing services. It also illustrates that coordinated approaches, adapted to the national health structures and local circumstances are needed. Countries need to identify evidence-based solutions suitable to their respective societal and cultural contexts. The exchange of knowledge, experiences and good practices, both nationally and internationally, will certainly be useful in the development and implementation of policies and programmes. Securing political commitment, raising public awareness as well as including innovative solutions (e.g. by using social media) are all essential to reach those who remain unaware of their HIV infection.

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LIST OF ABBREVIATIONS

AIDS	Acquired immunodeficiency syndrome	RKI	Robert Koch-Institut
ART	Antiretroviral therapy	STI	Sexually transmitted infection
CDC	Centre for Disease Control and Prevention, USA	TB	Tuberculosis
ECDC	European Centre for Disease Prevention and Control	TPC	Target population centre
EEA	European Economic Area	VCT	Voluntary counselling and testing
EU	European Union	UNAIDS	Joint United Nations Programme on HIV/AIDS
FOPH	Federal Office of Public Health, Switzerland	UNGASS	United Nations General Assembly Special Session on AIDS
FSW	Female sex workers	WHO	World Health Organization
HIV	Human immunodeficiency virus	WHO/EURO	WHO Regional Office for Europe
HBV	Hepatitis B Virus		
HCV	Hepatitis C Virus		
HPV	Human Papilloma Virus		
HSV	Herpes Simplex Virus		
HTS	HIV testing services		
IDU	Injection drug user		
LGBT	Lesbian, Gay, Bisexual and Transgender		
MSM	Men who have sex with men		
NGO	Non-governmental organisation		
PEP	Post-Exposure Prophylaxis		
PHE	Public Health England		
PICT	Provider initiated counselling and testing		
PLHIV	People living with HIV/AIDS		
PrEP	Pre-Exposure Prophylaxis		
RDT	Rapid diagnostics tests		

LIST OF FREQUENTLY USED TERMS

Anonymous testing	Patients can be tested for HIV without providing their name or contact information. Test results are recorded and reported and a unique code is assigned to the sample being tested. Only the respective patient can use this code.	Post-test counselling	A dialogue between a person and a health care provider to discuss the results of the HIV test and to offer additional HIV prevention guidance, linkage to treatment and care or other support services (if required)
Facility-based testing	HIV tests are conducted in healthcare facilities like specialized clinics, hospitals, public health centres etc.	Pre-test counselling	There is a dialogue between a person and a health care provider giving information about HIV testing and discussing the possible implications of HIV status test results for the individual, leading to an informed decision to take or not to take the test
Non-facility based testing	HIV tests are conducted in community settings, which are not part of the professional healthcare sector (e.g. schools, workplaces, clubs etc.) or during outreach activities in high-risk settings (e.g. mobile clinic).	Post-exposure prophylaxis (PEP)	PEP refers to antiretroviral medicines that are taken after exposure or possible exposure to HIV (e.g. by a needle stick injury, or by unprotected sex with a partner with HIV infection)
Opt-in	Patients are offered HIV testing and if they agree to testing, they must provide explicit consent	Pre-exposure prophylaxis (PrEP)	PrEP refers to antiretroviral medicines prescribed before exposure or possible exposure to HIV.
Opt-out	Patients are informed that HIV testing will be performed as part of their care, unless they explicitly decline	Provider initiated testing and counselling (PITC)	A health care provider recommends HIV testing and counselling to persons attending health care facilities as a standard component of medical care (e.g. for patients with a high risk of an HIV infection, patients with symptoms indicating a possible HIV-infection, patients with STIs or during pregnancy)
Partner notification	A voluntary process of informing the sex or drug taking partners of an individual with a diagnosed HIV infection about their possible exposure to the virus, encouraging them to attend HIV testing services		

LIST OF FREQUENTLY USED TERMS

Self-testing	A person administers the HIV test himself / herself and interprets the results in private (often called “home-testing”)
Self-sampling	A person takes the sample (saliva or blood) mails this personally to a laboratory.
Voluntary counselling and testing (VCT)	Individuals actively seek HIV testing and counselling (also known as “client-initiated testing and counselling”)
Window period	The time between HIV infection and detection of HIV-specific antigen and antibodies using serological assays (= seroconversion period). Testing during this period can result in false negative results

STUDY DESIGN

The study is based on national strategies, policies and guidelines of seven European countries. From May 1 to October 31 2017 an extensive web-based literature and document search for national policies on HIV testing was conducted, using WHO and ECDC databases, Google, government and NGO websites. Key experts in the field, including WHO, UNAIDS and ECDC staff, were contacted to identify additional policies and information. Representatives from the selected countries were also consulted to address the objectives stated above and to ensure that the latest information and results of the respective national strategies, policies and guidelines would be included.

Data sources

- Web-based literature and document review
- Consultation with experts in the field (WHO, UNAIDS, academia)
- Consultation with national policy makers

Aim

The aim of this study is to present, compare and discuss national strategies and programmes in the area of HIV testing.

Objectives

The specific objectives are

- To provide information about the current HIV / AIDS epidemiology in the selected countries.
- To present international declarations and strategies as well as the most relevant international and national guidelines on HIV-testing
- To identify and compare national HIV-testing strategies and policies from selected countries
- To give an overview of these policies and strategies
- To discuss specific aspects like self-testing, voluntary counselling and testing (VCT), partner notification or linkages with testing for other sexual transmitted infections
- To identify policy evaluations and indicators used
- To present good practice examples and challenges in the area of HIV-testing from the selected and additional countries

Limitations

The choice of countries is an important aspect in any comparison of national strategies and policies. A further critical aspect is the latency of the implementation of political decisions. Thus results achieved may in fact be partially due to many other factors, especially in this very multifaceted field with its high number of different stakeholders. As official documents are sometimes only published in the national language, some information might have been missed. In summary, some possible limitations to this study have been mentioned. However it is rather difficult to estimate exactly what impact these might have.

INTRODUCTION

The increasing availability of antiretroviral therapy (ART) has transformed the HIV infection into a manageable chronic condition for millions of people worldwide, enabling them to live longer and healthier lives. Levels of HIV incidence have been stagnating in many countries and studies suggest that a substantial proportion of new infections occur during acute and early infection (Baggaley, 2016).

Global progress has been achieved by scaling-up HIV testing services and the development and implementation of new testing approaches, by expanding provider-initiated testing and counselling in clinical settings and through community-based services as well as the use of rapid diagnostic tests. Despite these achievements there are still many people living with HIV who remain unaware of their infection (Easterbrook et al., 2015).

According to a 2017 report by the Joint United Nations Programme on HIV/AIDS (UNAIDS) 36.7 million people worldwide are estimated to be living with HIV but only 69% of them are aware of their serostatus. Therefore efforts have to be undertaken to further expand HIV testing services (HTS) to achieve earlier diagnosis and treatment and to prevent the spread of the infection to those at risk (UNAIDS, 2017d).

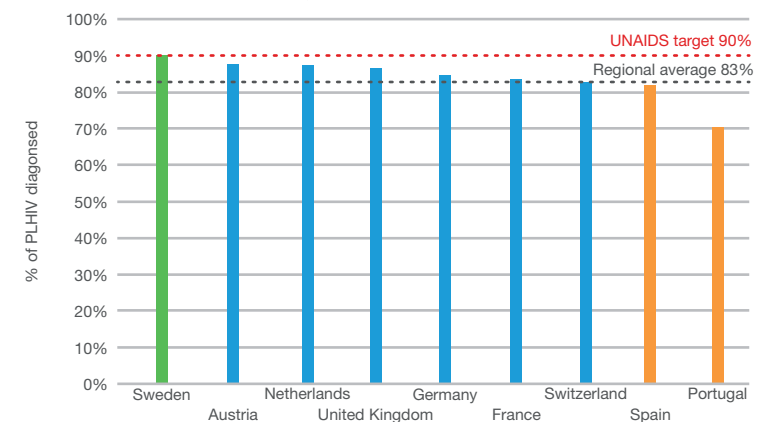
This will be critical in order to reach the United Nations “90-90-90” targets by 2020: 90% of all people living with HIV should be aware of their HIV status, 90% of all people diagnosed will have received sustained ART and 90% of all people on ART will have viral suppression (UNAIDS, 2014a).

This also applies to many European countries, where despite many programmes and campaigns, the proportion of people living with HIV (PLHIV)

who have not been diagnosed remains high. It has been estimated that on average about 1 in 6 people living with HIV in the European region are unaware of their serostatus (122.000 / 810.000). While a small number of European countries (e.g. Sweden) have reached the first 90%-goal, others are still far from this level (Figure 1) (ECDC, 2017c). This estimate for the EU/EEA region is lower than in 2005, when approximately 30% of PLHIV were unaware of their HIV infection. This can be partially explained by increasing and more targeted testing activities. In addition it seems that the annual number of new infections has been approximately the same as the number of new diagnoses, which – together with longer life expectancies of PLHIV – has led to a smaller proportion of undiagnosed people. New calculation methods and improved surveillance data have also had an impact on the overall estimations (Pharris et al., 2016).

Figure 1: Proportion of people living with HIV who have been diagnosed in selected countries

Source: ECDC, HIV testing, 2017 (ECDC, 2017a)



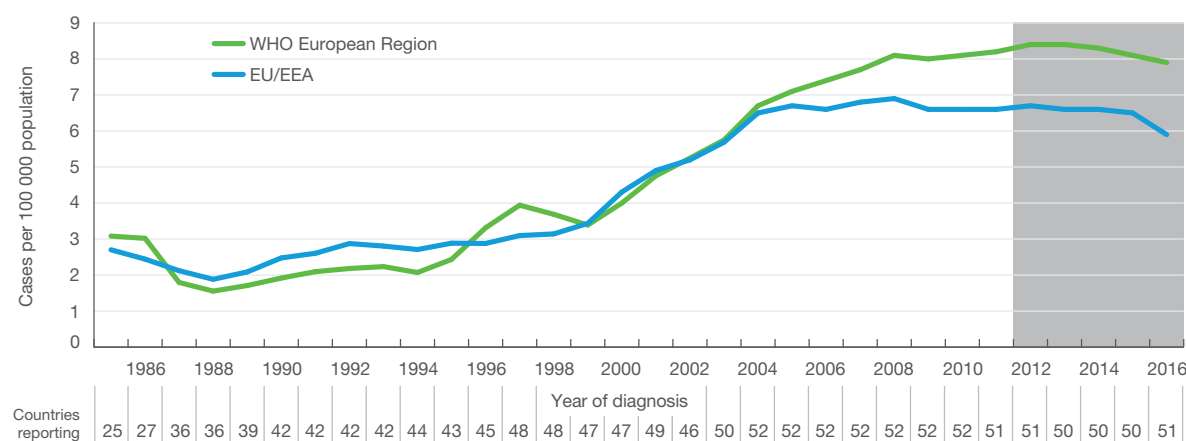
Overview of the HIV situation in selected countries

The WHO European Region has been the only region worldwide in which the number of new HIV infections has risen in recent years. By the end of 2016 the overall number of people living with HIV in the region had increased by 160.453 to more than 2 million, corresponding to a rate of 18.2 per 100.000 population. This was one of the highest annual increases by number since the 1980s. This trend has mainly been due to rising case numbers in eastern European and central Asian countries (Figure 2). In 2016 64.5% of the newly diagnosed HIV infections in the WHO European Region were recorded in Russia (ECDC, 2017e).

In the Western European countries selected for this study the HIV infection rate in the general population ranges between 0.08% in Sweden and 0.57% in Portugal. However this is likely to increase in the near future due to migration trends both from Eastern European and non-European countries (ECDC, 2016c).

ART coverage for people living with a diagnosed HIV infection in the Western European countries studied varies from 69% in Portugal to 96% in the United Kingdom. In the entire EU/EEA region, 17% of this population group has not yet received ART (ECDC, 2017d).

Figure 2: Rate of new HIV diagnosis per 100.000 population, by year and adjusted for reporting delay, in the EU/EEA and the WHO European Region, 1985-2016



Source: Adapted from:

HIV/AIDS surveillance in Europe 2017

* Data from Russia not included;

Reporting delays could lead to an increase of all data in this graph

Table 1: HIV statistics for all countries included in the study

HIV STATISTICS	France	Germany	Netherlands	Portugal	Sweden	Switzerland	UK
General population (in Million) ¹	64.39	80.69	16.92	10.35	9.8	8.3	64.71
Persons living with HIV (2015) ²	153.100	84.700	22.900	59.365	7.718	15.200 ⁴	101.200
% of PLHIV in the general population	0,24%	0,1%	0,14%	0,57%	0,08%	0,2%	0,16%
90 – 90 – 90 TARGETS (2017)³	2013	2015	2015	2014	2015	2012	2015
1 st 90: % of PLHIV knowing their status	84%	85%	88%	70%	90%	82%	87%
2 nd 90: % of PLHIV diagnosed and on ART	89%	84%	88%	67%	95%	91%	96%
3 rd 90: % of PLHIV, ART with viral suppression	91%	93%	93%	78%	95%	97%	94%
NEW DIAGNOSES (2015)²							
New HIV diagnoses	5219	3419	745	1030	429	539	5164
New HIV diagnoses / 100.000 population	7.8	4.2	4.4	10.0	4.4	6.4	7.9
Male	10.7	6.7	7.6	15.0	5.5	10.1	12.2
Female	5.0	1.7	1.2	5.4	3.3	2.7	3.7
By mode of transmission							
• MSM	29.4%	50.4%	67.1%	35.5%	31.7%	42.1%	46.4%
• Heterosexual contact	38.3%	25.3%	25.6%	56.9%	47.1%	28.9%	33.4%
• Injecting drug use (IDU)	1.8%	3.7%	0.13%	2.9%	6.1%	2.41%	2.1%
• Other or undetermined mode	30.5%	20.5%	7.1%	4.6%	15.1%	26.5%	18.1%

Sources:

1 World Population Prospects, 2015 Revision, (UNDESA, 2015) || 2 HIV/AIDS surveillance in Europe 2016, (ECDC, 2017e) || 3 Continuum of HIV care, (ECDC, 2017)

4 The HIV care cascade in Switzerland, (Kohler, 2015)

* In regard to data on transmission modes, reporting is often incomplete or delayed. This information is presented here to provide a general impression of the situation.

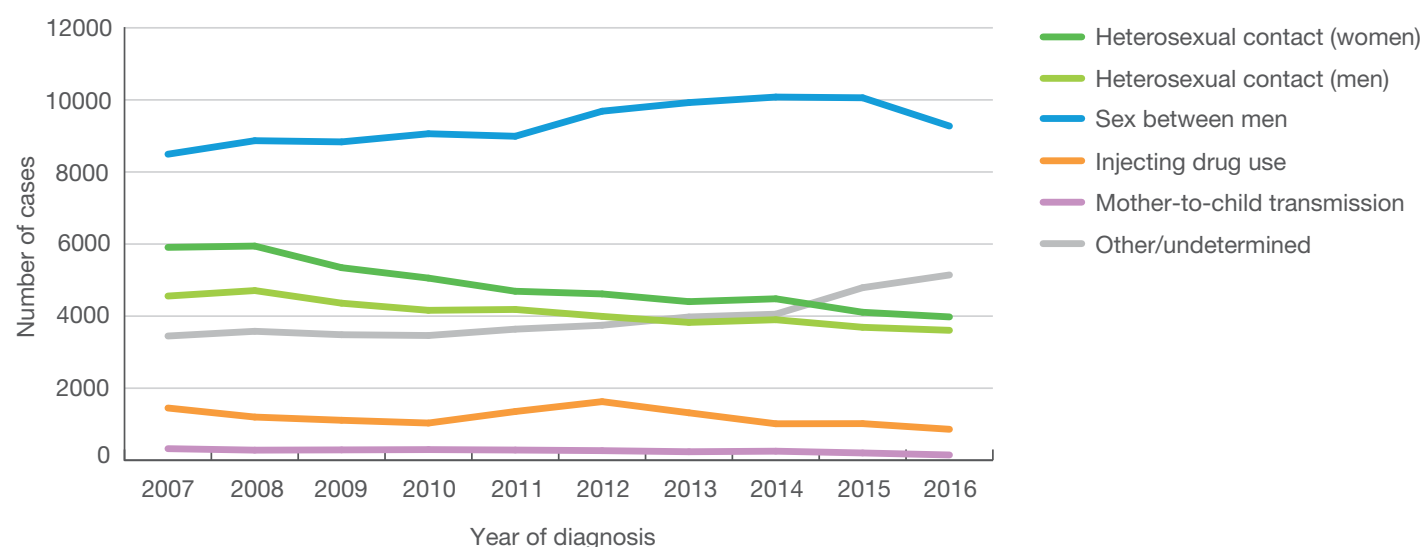
The HIV infection rates (per 100.000 population) in the selected countries range between 4.2 in Germany and 10.0 in Portugal. A significant gender difference can be observed in countries with a high percentage of transmission in the MSM group. In the Netherlands, for example, 67.1% of HIV infections are transmitted by men who have sex with men, leading to an infection rate for men of 7.6 per 100.000 population, while the infection rate for women is only 1.2 per 100.000 population.

The reported HIV transmission modes in the Western European region show that the number of HIV diagnoses in the MSM group remains high and predominant with 41% of all new HIV infections with a known mode of transmission (Figure 3). Heterosexual contacts account for 33% of all new

HIV infections, but the number of cases caused by this transmission mode has been decreasing for both women and men during the past decade. 3% of those newly diagnosed were infected through injecting drug use. These developments and the percentages listed in Table 1 illustrate the diversity and trends in the epidemiology of HIV in the Western European region (ECDC, 2017e).

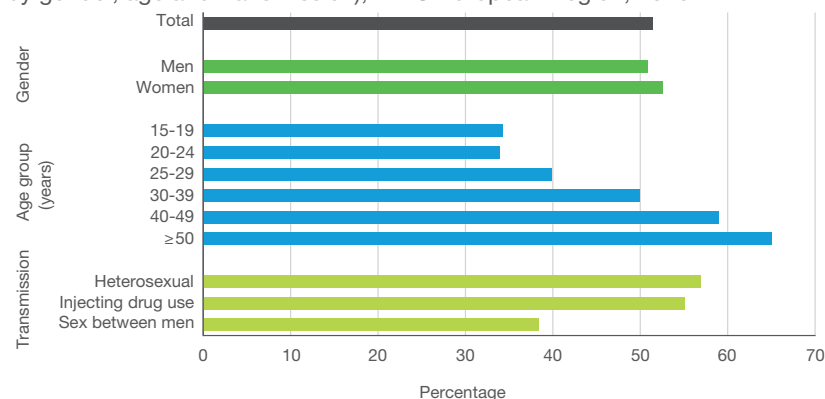
Figure 3: New HIV diagnoses, by transmission mode and year of diagnosis, adjusted for reporting delay, Western Europe, 2007–2016

Source: HIV/AIDS Surveillance in Europe 2017 – 2016 data (ECDC, 2017e)
Data from Italy and Spain excluded due to increasing coverage of national surveillance during the period.



Of those being diagnosed in the EU/EEA region, more than half of the cases (51%) are diagnosed late (CD4 cell count of $<350/\text{mm}^3$) and 30% of cases are even diagnosed with an advanced HIV infection (CD4 cell count of $<200/\text{mm}^3$) (Figure 4). This applies to the populations most at risk of becoming infected with HIV, particularly people over 50 years of age, mainly due to low testing rates in these groups. In 2016 55% of people injecting drugs and 57% of heterosexual cases coming from countries with generalised HIV epidemics in the EU/EEA countries, who were diagnosed at a late stage or even with an advanced HIV infection. In comparison to this only 38% of those who acquired HIV through sex between men presented with a CD4 cell count of $<350/\text{mm}^3$ (Figure 5).

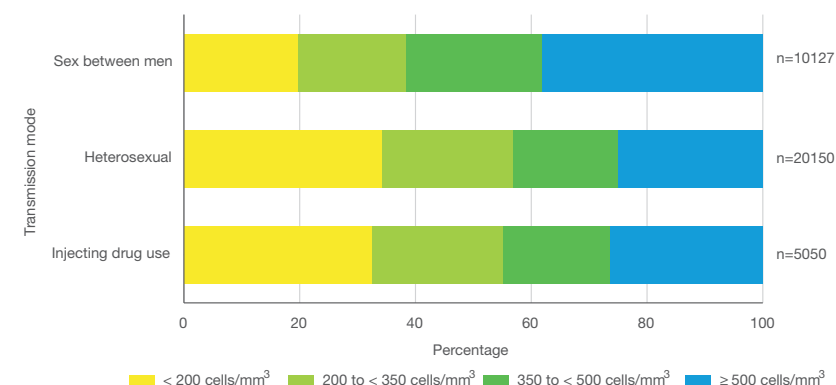
Figure 4: Proportion of persons diagnosed late (CD4 cell count $< 350/\text{mm}^3$ by gender, age and transmission), WHO European Region, 2016



Source: Adapted from: ECDC / WHO EURO, HIV/AIDS surveillance in Europe 2017 – 2016 data, (ECDC, 2017e)

Overall late presentation remains a significant problem in the EU/EEA region. According to ECDC two out of three people with AIDS in the region receive their diagnosis within only three months of being diagnosed with HIV. The average time between the HIV infection and diagnosis is about three years, a period of lost opportunities for access to treatment and care and the prevention of further transmission of the virus (ECDC, 2017e).

Figure 5: New HIV diagnosis, by CD4 cell count per mm^3 at diagnosis and transmission mode, WHO European Region, 2016



Source: Adapted from ECDC, HIV/AIDS surveillance in Europe, 2016 (ECDC, 2017e); No data from Hungary, Iceland, Latvia, Monaco, Poland, Russia, San Marino, Turkmenistan, Ukraine and Uzbekistan.

HIV testing situation in Europe

Many European countries no longer collect systematic data on HIV tests systematically. The collection of data on the number of HIV tests performed is difficult due to various reasons such as the existence of multiple and unlinked databases (e.g. in Sweden), an increasing trend towards community-based testing services and self-testing opportunities in some countries like France and the UK. The European Center for Disease Control and Prevention (ECDC) states that HIV test data for Western Europe “are too sparse to provide a meaningful assessment” and comparability of collected data on tests performed is therefore limited. In addition it should be noted that increasing the numbers of tests performed does not necessarily generate higher case detection rates, if the focus of these tests is not on key populations with high risk of HIV infection (ECDC, 2016c).

According to a ECDC multicountry analysis the key challenge in relation to HIV testing in Europe and Central Asia is to increase the low testing rates among populations most at risk of HIV (e.g. men who have sex with men, sex workers, injecting drug users and prisoners). National experts believe that for an effective provision of HIV testing services the availability of community-based services, sustainable funding, and health professionals’ knowledge and attitudes are crucial, especially in relation to services offered to key populations. In addition fear, stigma and discrimination within these populations, but also among health professionals, need to be reduced, confidentiality guaranteed, and laws and policies evaluated as in some countries criminalisation remains a barrier in the provision and uptake of testing (ECDC, 2017a).

II. United Nations

HIV/AIDS has become one of the leading health issues for the work of international organizations like the UN, WHO and other UN agencies. The **UN Millenium Declaration** emphasized the need to reverse the spread of HIV/AIDS and to help build capacity to tackle the spread of this pandemic and other infectious diseases (UNGA, 2000).

In response to the accelerating epidemic and its global impact, the United Nations General Assembly held a special, high-level session on HIV/AIDS in New York in June 2001. The aim of this session was to intensify international collaboration and to mobilize necessary resources for the fight against the epidemic. In the **Declaration of Commitment on HIV/AIDS** expanded access to voluntary and confidential counselling and testing (VCT) was recognized as being essential for an effective HIV prevention strategy (UNGA, 2001).

Under the theme **Uniting the world against AIDS** the UN General Assembly held a High-Level meeting on AIDS in May 2006 to review the progress made, to consider additional recommendations and to renew the political commitment. In the outcome document, the **Political Declaration on HIV/AIDS (60/262)**, Member States pledged to promote access to HIV/AIDS education, information, VCT and related services (UNGA, 2006).

In 2011 the UN General Assembly adopted a **Resolution to intensify the efforts to eliminate HIV and AIDS**. This included a commitment to significantly expand and promote voluntary and provider-initiated HIV testing and counselling (PITC) services. In addition national testing promotion

campaigns for HIV and other sexually transmitted diseases were to be intensified (UNGA, 2011).

In June 2016 the UN General Assembly adopted its latest political declaration on HIV and AIDS, **On the Fast-Track to Accelerate the Fight against HIV and to End the AIDS Epidemic by 2030**. Ensuring access to testing and treatment has been highlighted as one key aspect requiring more commitment and action:

“Commit to using multiple strategies and modalities, including, when possible, voluntary, confidential, fully-informed and safe community-based testing, according to national context, to reaching the millions of people who do not know their status, including those living with HIV and to providing pre-test information, counselling, post-test referrals and follow-up to facilitate linkages to care, support and treatment services, including viral load monitoring and to addressing socioeconomic barriers to testing and treatment, including legal, regulatory barriers to community testing, and commit to expanding and promoting voluntary and confidential HIV testing and counselling, including provider-initiated HIV testing and counselling and to intensifying national testing promotion campaigns for HIV and other sexually transmitted infections;” (UNGA, 2016)

III. World Health Organization

WHO has been involved in the fight against HIV/AIDS since the discovery of the HI-Virus in 1983. The organization has published a large number of normative guidelines, technical briefings and other documents, providing support to its Member States in formulating and implementing policies and programmes for HIV prevention, treatment, care and support services. WHO has also been co-sponsoring and working closely with the Joint United Nations Programme on HIV/AIDS (UNAIDS), aligning the strategies and programmes of the two organizations.

In the **Global Health Sector Strategy on HIV 2011-2016**, WHO stated the need to rapidly expand access to diversified HIV testing and counselling services. In addition it was emphasized that testing and counselling must be voluntary, confidential and accompanied by appropriate counselling, ensuring the protection and promotion of the human rights of clients, regardless of setting or testing modality (WHO, 2016a).

In May 2016 the 69th World Health Assembly (WHA) endorsed the **Global Health Sector Strategy on HIV 2016-2021** together with sector strategies to cover viral hepatitis and sexually transmitted infections (STI). This strategy highlights the necessity of renewed political commitment, additional resources, and technical and programmatic innovations. New HIV testing approaches, including self- and community-based testing and new quality-assured testing technologies are promoted in this strategy to ensure that all people living with HIV are aware of their serostatus. A strategic focus of HIV testing services is believed to be essential for reaching those most at risk and for diagnosing and treating patients early (WHO, 2016a).

Table 2: HIV Testing Actions, WHO Global Health Sector Strategy on HIV 2016-2021 (WHO, 2016a)

HIV Testing

FAST-TRACK ACTIONS FOR COUNTRIES

Diversify testing approaches and services by combining provider-initiated and community-based testing, promoting decentralization of services and utilizing HIV testing services to test for other infections and health conditions.

Focus testing services to reach populations and settings where the HIV burden is greatest and to achieve equity.

Prioritize the expanded coverage of early infant diagnosis technologies.

Ensure that HIV testing services meet ethical and quality standards.

FAST-TRACK ACTIONS FOR WHO

Regularly update consolidated guidance on HIV testing and testing for common co-infections, rapidly integrating guidance on new testing approaches, strategies and diagnostics.

Support countries to implement quality assurance programmes for testing, guided by data on misdiagnosis and misclassification.

Support expansion of paediatric HIV testing through updated guidance and technical support to countries, including early infant diagnosis and testing in low-prevalence settings.

Source: WHO, 2016a

In 2015 the new **WHO Consolidated Guidelines on HIV Testing Services** were published, highlighting the 5 principles applicable to all models of HIV testing services and in all circumstances: **Consent, Confidentiality, Counselling, Correct Results and Connection** (see box page 25). The guidelines provide comprehensive evidence-based recommendations and offer guidance to countries to develop and implement a mix of high quality HIV testing services appropriate for the respective epidemic context, key populations affected and local health systems (WHO, 2015).

To include new evidence and to contribute to closing the testing gap WHO has published updated **Guidelines on HIV self-testing and partner-notification** in 2016. These documents provide guidance on how HIV self-testing and assisted HIV partner notification services can be integrated into community-based and facility-based HTS approaches and how these can be adapted to specific population groups (WHO, 2016b). WHO strongly recommends offering HIV self-testing as an additional approach to HIV testing services as HIV self-testing is believed to be “an empowering and innovative way to reach first-time testers, undiagnosed people living with HIV or those at ongoing risk requiring frequent testing” (WHO, 2016d). WHO also recommends offering voluntary partner notification services as part of a comprehensive package of testing and care offered to people living with HIV (WHO, 2016c).

In addition WHO has previously published several guidelines and other documents related to HIV testing, for example:

- Guidance for HIV testing and counselling and care for adolescents living with HIV (2013)
- Guidance on couples HIV testing and counselling (2012)
- Guidelines for using HIV testing technologies in surveillance (2010)
- Policy statement on HIV testing and counselling in health facilities for refugees, internally displaced persons and other persons of concern (2009)
- HIV testing and counselling in prisons and other closed settings (2009)
- Guidance on testing and counselling for HIV in settings attended by people who inject drugs (2009)

Source: WHO, HIV/AIDS guidelines, (WHO, 2017a)

1. Consent

HIV testing is a choice. Everybody should be given the opportunity to test for HIV, but an individual's decision to take an HIV test must always be voluntary. People being offered testing for HIV must give informed consent. This means that they need to be informed of the process for HIV testing and confirming the results, the services that are available depending on the results and their right to refuse testing without consequences. Mandatory, compulsory or coerced testing is never appropriate, regardless of where that coercion comes from: health-care providers, partners, family members, employers, law enforcement officials or others.

2. Confidentiality

Testing services must be **confidential**, meaning that the test results and the content of discussions between the person tested and the testing provider, counsellor and/or other health-care workers will not be disclosed to anyone else without the consent of the person tested.

3. Counselling

Appropriate and high-quality brief pre-test information and post-test counselling tailored to the person and the test results must be available.

4. Correct status

It is critical that the HIV status delivered to individuals is correct. To ensure that test results are accurate, all testing should be performed in accordance with WHO or national quality assurance systems and standards, including the use of the appropriate testing strategy based on the characteristics of the local epidemic, and with a validated testing algorithm. The test results must be communicated to the person tested unless that person subsequently decides that they do not wish to receive the results.

5. Connection

Linkage to HIV prevention, treatment and care and support services should be supported through concrete and well-resourced patient referral, support and/or tracking systems.

Source:

WHO Consolidated Guidelines on HIV Testing Services, (WHO, 2015a)

WHO – Regional Office for Europe

In Europe the 2004 **Dublin Declaration on Partnership to Fight HIV/AIDS in Europe and Central Asia** has been a key document for both the national and international response to the epidemic. It outlined actions for governments related to leadership, prevention, treatment and care as well as partnerships in the 53 countries of the WHO European Region. Scaling up and ensuring access to voluntary HIV counselling and testing were some of the actions mentioned in the declaration (WHO/EURO, 2004). In 2010 WHO/EURO published a policy framework on **Scaling up HIV testing and counselling in the European Region** emphasizing the importance of linking these services to broader efforts to achieve universal access to comprehensive, evidence-based HIV prevention, treatment, care and support (WHO/EURO, 2010). The main principles of this document were also used as the basis of the HIV testing and counselling section in the **European Action Plan on HIV/AIDS 2012-2015** (Table 3) (WHO/EURO, 2011).

The WHO Regional Committee for Europe adopted an **Action plan for the health sector response to HIV in the WHO European Region** in 2016 urging Member States to strengthen HIV prevention, by promoting comprehensive interventions and tools, including innovative approaches to HIV testing. In addition Member States have been encouraged to expand targeted HIV testing by focusing on key populations in settings with a high HIV prevalence, to ensure an early linkage to treatment, care and prevention services and to promote rapid HIV testing. These aims could be achieved through health care provider initiated testing, testing of target populations through community and outreach services and lay service providers as well as through testing in closed settings and self-testing (WHO/EURO, 2016).

Table 3: Main principles for HIV testing and counselling, (WHO/EURO, 2011)

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.

Expanded HIV testing and counselling must be tailored to different settings, populations and client needs.

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.

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.

Rapid HIV tests should be used where appropriate.

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.

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

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.

In each country, consultations should be undertaken to formulate plans for expanded HIV testing and counselling based on this framework.

Efforts to expand access to HIV testing and counselling must be carefully monitored and evaluated.

IV. UNAIDS

The Joint United Nations Programme on HIV/AIDS (UNAIDS) has estimated that only 70% of the 36.7 million people living with HIV worldwide are aware of their serostatus (UNAIDS, 2017a). Therefore efforts have been made to expand HIV testing services to achieve earlier diagnosis and treatment for the individual and to prevent the spread of the infection to those at risk (UNAIDS, 2015a). This will be critical in attaining the United Nations “90-90-90” targets.

The United Nations “90-90-90” targets aim at

- by 2020, 90% of all people living with HIV will know their HIV status
- by 2020, 90% of all people diagnosed will receive sustained antiretroviral therapy (ART)
- by 2020, 90% of all people on ART will have viral suppression.

(UNAIDS, 2014a)

In the **UNAIDS Strategy 2016 – 2021 – On the Fast-Track to end AIDS** the urgency of closing the testing gap is emphasized and countries are encouraged to develop targeted testing strategies and to offer voluntary HIV testing services accessible for all people at risk of a HIV infection (UNAIDS, 2016a).

In November 2015 UNAIDS launched **ProTest HIV**, a global initiative to encourage young people to get tested for HIV. By working with young people and Young ProTest HIV ambassadors UNAIDS has been aiming to establish more integrated youth-friendly services and to reduce HIV-related stigma and discrimination (UNAIDS, 2015b).

UNAIDS has also been promoting HIV self-testing and, together with WHO, published a short technical update in 2014. HIVST can be beneficial for both the general population and for health workers in settings with a high prevalence of HIV as well as for key populations at higher risk in all settings. UNAIDS and WHO recommend adapting national testing policies and regulations to include HIVST linked to counselling services (UNAIDS, 2014b).

In its 2016 **Prevention Gap Report** UNAIDS emphasized the need for scaling up HIV testing and treatment together with a “much stronger primary prevention response”. Stigma, discrimination and other human rights violations which prevent people from seeking testing and treatment still have to be tackled in many countries. In addition community engagement in HIV testing and treatment programmes has to be increased and innovative HIV testing strategies such as self-testing and partner-supported testing expanded (UNAIDS, 2016b).

In April 2017 the UNAIDS Scientific and Technical Advisory Committee (STAC) called for UNAIDS to lead global efforts for a **“HIV testing revolution”** and for significant increases in political and financial support in this area in order to reach the 90-90-90 targets (UNAIDS, 2017c).

“Scaling up access to HIV testing is critical to ending the AIDS epidemic by 2030, offering everyone the right to know their HIV status through high-quality national HIV testing programmes that respect every individual's dignity and human rights.”

Michel Sidibé UNAIDS Executive Director

V. European Union

The **Dublin Declaration on Partnership to Fight HIV/AIDS in Europe and Central Asia** signed in 2004, emphasized the commitment to act collectively and to closely monitor and evaluate the implementation and progress of the outlined actions. Among the action points mentioned in this declaration were the availability of testing and counselling services and their accessibility, affordability and acceptability for those people most at risk (WHO/EURO, 2004). The Dublin Declaration was reaffirmed in the **Vilnius Declaration on Measures to Strengthen the Responses to HIV/AIDS in the European Union and in Neighbouring Countries**. This declaration was the result of a Ministerial meeting with representatives of Governments of the European Union and neighbouring countries as well as relevant international partners in Vilnius, Lithuania, in September 2004 (EU, 2004).

The European Commission presented its policy priorities regarding HIV in Europe in a **Communication and Action Plan for Combating HIV/AIDS in the European Union and neighbouring countries** (EU, 2017). One key target in the latest Action Plan is achieving universal “access to comprehensive and integrated prevention, and early testing services and commodities for most at risk populations including sex workers and prisoners” (EC, 2014). To help with policy implementation and to strengthen cooperation among its member countries, civil society and international organisations, the European Commission has established an **HIV/AIDS Think Tank** as an exchange forum for exchange as well as an **HIV/AIDS Civil Society Forum** with major European networks and NGOs to support the work of the Think Tank (EU, 2017). The European Commission has also supported the **European HIV-**

Hepatitis Testing Week, launched by the HIV in Europe initiative in 2013 and now held annually in November. The aim of this initiative is to raise awareness of the benefits of HIV and hepatitis testing especially in high-risk groups across Europe involving more than 500 partner organizations in more than 50 countries (HIV-in-Europe, 2017a). The **Optimising Testing and Linkage to Care for HIV Across Europe** project (OptTEST) conducted by the HIV in Europe initiative and co-funded by the EU aimed at reducing the number of undiagnosed people living with HIV and promoting timely treatment and care (HIV-in-Europe, 2017c).

The European Commission has been co-funding the **Euro HIV Early Diagnosis and Access to Treatment Project** (EURO HIV-EDAT) to provide a better understanding of the role and impact of community-based voluntary counselling and testing services, to explore new HIV testing strategies based on innovative technologies and to increase early diagnosis and treatment for HIV and other sexually transmitted diseases in vulnerable groups. The aim of this project was to generate harmonized monitoring and evaluation data from community-based testing centres across Europe using indicators and instruments developed by the **COBATEST** project. In addition research was carried out into the acceptability, feasibility and effectiveness of innovative strategies, such as point-of-care technologies for diagnosis, HIVST and web based outreach and counselling approaches (EDAT, 2017). The EURO HIV-EDAT and the OptTEST projects have ended in September 2017 and the newly launched **INTEGRATE** Joint Action project, which is co-funded by the 3rd Health Programme of the European Union, is partially based on these projects (HIV-in-Europe, 2017b).

European Centre for Disease Prevention and Control

The European Centre for Disease Prevention and Control (ECDC) has been responsible for publishing a biannual progress report on the action points of the Dublin Declaration (WHO/EURO, 2004). The **European Network for HIV/AIDS surveillance** is coordinated by the ECDC together with the WHO Regional Office for Europe collecting data from all of its 53 Member States in the European Region. An annual surveillance report is published by the ECDC including information on HIV testing such as the number of HIV tests performed from countries with systematic data collection (ECDC, 2016c).

In 2010 the ECDC prepared an evidence-based guidance publication (**HIV testing: Increasing uptake and effectiveness in the European Union**) in response to the rising number of HIV infections and the problem of late diagnosis in many European countries to provide information concerning the development, monitoring and evaluation of national HIV testing strategies and programmes (ECDC, 2010a). This publication was a technical report based on findings and conclusions of a systematic literature review and evidence synthesis (ECDC, 2010b).

The HIV in Europe initiative conducted an **Evaluation of the impact of the ECDC guidance on HIV testing** in 2016, which was commissioned by the ECDC. This evaluation showed the diversity of approaches used by those EU / EEA Member States covered by the survey. At the national level 68% of countries had an HIV strategy / policy in place that included recommendations on HIV testing, 57% were using a national HIV testing guideline document and 50% were applying HIV testing guidelines issued by professional societies. While 90% of the survey respondents considered it

important to have an EU level HIV testing guidance, only 57% indicated that their present national guidelines were closely or in some way aligned with the 2010 ECDC HIV testing guidance. Regular updates have been suggested to increase the relevance and use of this guidance document, including new evidence, technologies and other factors in the rapidly evolving field of HIV testing (ECDC, 2016b).

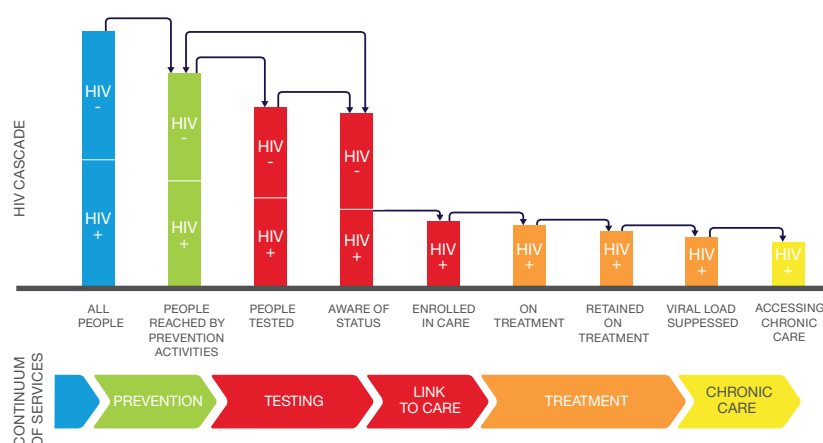
A **Special report on HIV testing** was published in April 2017 highlighting the continuing challenges in the field of HIV testing in European and Central Asian countries. Among these challenges were low testing rates in the populations most at risk of HIV, the high percentage of people living with HIV unaware of their infection and the high proportion of people diagnosed late or very late. A number of countries still lack national HIV testing guidelines or up-to-date guidelines (ECDC, 2017a)

A modelling analysis, supported by the ECDC HIV/AIDS Surveillance and Dublin Declaration networks, has emphasized the diversity of HIV incidence and in the undiagnosed population across Europe underlining the need for increased availability of strong national estimates to guide and evaluate testing and prevention practices. While a general positive trend towards lower numbers of people living with undiagnosed HIV has been observed, differences across the EU/EEA persist and the high proportion of late diagnosis remains a huge challenge. The authors of the analysis therefore call for additional efforts increasing the availability and uptake of HIV testing and rapid linkage to HIV treatment in the EU/EEA countries (van Sighem et al., 2017).

1. NATIONAL STRATEGIES, POLICIES AND GUIDELINES

The provision of comprehensive HIV testing services is crucial for reaching millions of people with undiagnosed HIV infection and for achieving the 90-90-90 targets. WHO has been supporting its Member States to address gaps in the cascade of prevention, testing and treatment services (Figure 6).

Figure 6: The continuum of HIV services and retention cascade



Source: WHO Global Health Sector Strategy for HIV, 2016 (WHO, 2016a)

National ministries, authorities and non-governmental organizations have been using a range of approaches to tackle the challenges and barriers limiting the uptake of HIV testing services. This study will describe, compare and discuss the main approaches and measures taken by the selected countries.

HIV testing programmes in many countries need to be redesigned as these were conceptualized at a time when ART wasn't available for most people living with HIV. New approaches such as self-testing, multi-disease testing, community campaigns and special programmes for target groups, including migrants, refugees and asylum seekers, are being developed and implemented (Brostrom et al., 2014).

Over the past decade innovative approaches, such as low-cost rapid diagnostic tests, have been used to expand HIV testing services, enabling new testing opportunities in clinics, communities and homes for professionals as well as for lay providers (WHO, 2017b). In most countries HIV testing approaches are either included in a national HIV strategy or policy, a national guideline document or are part of guidelines on HIV testing issued by professional societies (ECDC, 2016a).

These approaches vary, responding to the respective national epidemiological situation and health systems context. A number of governmental and non-governmental organizations are involved in the organization and coordination of HIV testing services and campaigns. Key issues in this area are the provision of and access to these services, the testing process itself and the counselling and further treatment offered.

In addition policy makers need to take practical issues into consideration e.g. the kind of tests being used, opt-in or opt-out policies, cost coverage and the legalisation of self-testing. Monitoring and evaluating HIV testing policies are important to identify challenges and good practice examples.

HIV Testing

HIV testing approaches vary between countries. Depending on the national HIV situation, strategies and policies have been developed, technical guidelines have been published by national ministries, health authorities or medical associations and HIV testing services have been set up. These include testing opportunities in various settings, counselling services and appropriate HIV prevention, treatment and care services. Monitoring testing services and evaluating national HIV testing policies, including their cost-effectiveness are further aspects covered in this study.

General structure of the following country chapters

-  **National HIV Situation**
-  **National HIV Strategy**
-  **National HIV Prevention Activities**
-  **National HIV Testing Strategy / Policy**
 - Coordination of HIV Testing
-  **Access**
 - Counselling
 - Partner notification
-  **Process**
 - HIV Testing Guidelines
 - Window period
 - Costs
-  **Treatment, PEP and PrEP**
-  **Policy Evaluations**
-  **Good Practice Examples**
-  **Challenges**

1.1 FRANCE



In 2016 an estimated 153.100 people were living with HIV in France, accounting for about 0.24% of the overall population. 89% of those diagnosed with HIV were on ART. Almost 16% of PLHIV were still unaware of their infection and were therefore likely to transmit the virus.

Table 4: HIV situation in France

HIV STATISTICS	France
General population (in Million) ¹	64.39
Persons living with HIV	153.100
% of PLHIV in the general population	0.24%
90 – 90 – 90 TARGETS²	2013
1 st 90: % of PLHIV knowing their status	84%
2 nd 90: % of PLHIV diagnosed and on ART	89%
3 rd 90: % of PLHIV, ART with viral suppression	91%
NEW DIAGNOSES³	5219
New HIV diagnoses per 100.000 population	7.8
• Male	10.7
• Female	5.0
By mode of transmission⁴	
• MSM	44 %
• Heterosexual contact	54 %
• Injecting drug use (IDU)	1 %
• Other or undetermined	1 %

Sources:

1 World Population Prospects, 2015 Revision, (UNDESA, 2015)

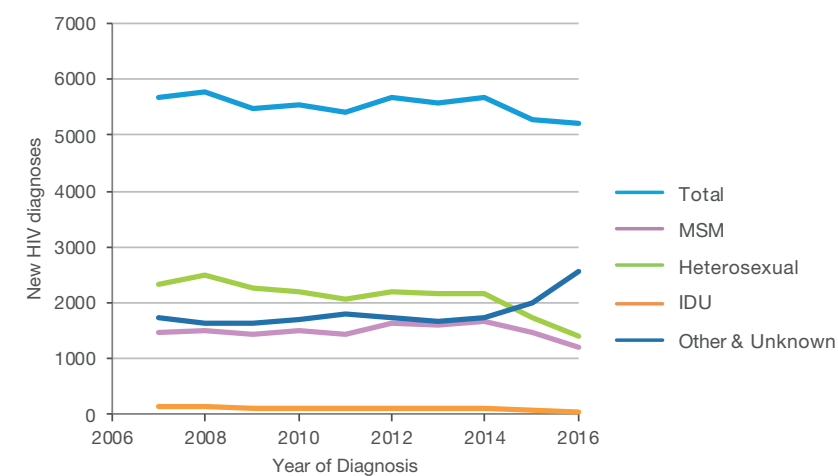
2 Continuum of HIV care, (ECDC, 2017)

3 HIV/AIDS Surveillance in Europe 2017 – 2016 data, (ECDC, 2017e)

4 Dépistage de l'infection par le VIH en France en 2016, SPF, 2017 (SPF, 2017a)

The HIV epidemic in France is considered to be a concentrated epidemic, affecting certain population groups in particular. Men who have sex with men account for 44% of new infections, followed by migrant women (23%) and migrant men (16%) especially from Sub-Saharan African countries. 14% were heterosexuals originating from France and about 1% injecting drug users.

Figure 7: New HIV diagnoses, total and by mode of transmission, France, 2007-2016



Source: HIV/AIDS Surveillance in Europe 2017 – 2016 data, (ECDC, 2017e)

Since April 2016 the reporting of an HIV diagnosis via a new web-based application (e-Do) has become mandatory for physicians and biologists in France. Reporting times have significantly been reduced, enabling quicker calculations and trend identification (SPF, 2015).

Despite a slight decrease by about 5% since 2013, the number of new HIV diagnoses remains high with about 6000 people being diagnosed in 2016. 27% of those were diagnosed at an advanced stage of the infection and 43% had never been tested before (SPF, 2017b).

In contrast to most other countries included in this study, France has been collecting systematic data on the number of HIV tests performed. Since 2006 almost 5.2 million HIV tests have been conducted annually in France (excluding unlinked anonymous testing and testing of blood donations). This is equivalent to 80.6 tests per 1000 population per year. Only a small number of countries in the EU/EEA region have reported higher rates (ECDC, 2016c).

In 2016 5.4 million HIV tests were performed in France, 6% of these were free anonymous tests and 10.667 HIV tests showed a positive result. The proportion of positive HIV tests was 3.6 per 1000 among anonymous tests and 1.9 per 1000 in confidential testing. In 2016, 52 authorized organizations performed approximately 56.300 HIV rapid tests in community-based settings (TROD), of which 491 were found positive (8.7 per 1.000 tests). In addition 74.651 HIV self-test screening devices had been sold in pharmacies (SPF, 2017a)

Studies in France have shown that 52% of men who have sex with men and 35.5% of migrants from high prevalence countries have had an HIV test within a 12-month period and that 94% of injecting drug users have had at least one HIV test in their life (ECDC, 2017c).

National HIV Strategy

The **National Plan to combat HIV/AIDS and sexually transmitted diseases 2010-2014** was the 5th strategic plan in this area since the 1990s. It was developed by the French Ministry of Social Affairs and Health together with a broad range of stakeholders like healthcare professionals, NGOs, the French National AIDS Council and a special Steering Committee, chaired by the Director General of Health (FRA, 2010).

The plan was based on three main principles selected to support its implementation by national and regional actors:

1. Structured to be easily integrated into Regional Health Plans set up by 26 Regional Health Agencies created in 2009
2. Population-based approach taking the HIV/STI epidemiology into account
3. Emphasizing the fight against discrimination and for equality, securing human rights and access to prevention, treatment and care

The eight main goals of the strategy are

- 50% reduction of the HIV incidence
- 50% reduction of AIDS incidence
- 50% reduction of a late HIV diagnosis
- 20% reduction of AIDS mortality
- Reduction of Gonorrhoea incidence
- Reduction of Syphilis incidence
- Reduction of Chlamydia and Herpes Simplex Virus prevalence
- Reduction of Papillomavirus incidence and prevalence

In 2017 a **National Sexual Health Strategy 2017-2030 Agenda** was published aiming at ending the AIDS epidemic before 2030 and at reaching 95% in all of the three UNAIDS goals by 2020. Encouraging the use of self-tests for HIV screening is one of the new approaches highlighted in this strategy (FRA, 2017).

National HIV Prevention Activities

Reinforcing and diversifying STI and HIV prevention are among the main priorities of the new French National Sexual Health Strategy. The prevention approaches combine socio-behavioural and biomedical dimensions and are mainly focused on empowering the individual to reduce the personal risk of exposure to STIs and HIV. The use of condoms, pre- and post-exposure prophylaxis and anti-retroviral treatment to reduce the risk of transmission are key preventative elements supported by national authorities and NGOs. In addition counselling services are being offered encouraging people at risk to take STI and HIV tests more frequently (FRA, 2017).

In this context special attention is being given to the most vulnerable populations and those most exposed to HIV, Hepatitis B and C as well as STIs like MSM, migrants originating from sub-Saharan Africa, drug users and people involved in prostitution as well as prisoners. Recognizing that these groups are often unaware of existing prevention measures and counselling services, Santé publique France has, for example, implemented a communication campaign highlighting the diversity of prevention tools and their use with respect to various MSM life stages. In 2016 a special website (Sexosafe.fr) was set up, offering a wide range of information on

sexual health and tools to prevent HIV and other STIs. In addition the campaign used public spaces, community centers, the gay press and social media tools to reach younger age groups in particular (SPF, 2016).

Another, very heterogeneous population group, which is being particularly addressed in the 2017 National Sexual Health Strategy, are migrants, especially those from highly endemic regions. According to the 2012 national census approximately 5.7 million foreign-born people live in France, 40% of these have acquired French citizenship. 23% of new HIV infections in France are attributable to female, heterosexual migrants, who often face problems linked to sexual and reproductive health. Therefore a number of targeted prevention efforts have been introduced as part of an overall prevention and healthcare approach, including screening and vaccination programmes, the creation of primary care centers offering family planning and other healthcare services as well as the implementation of “health appointments”, systematically being offered to newly arrived migrants within four months of their arrival in France. Other HIV prevention activities in France have been specifically targeted towards transgender people, prostitutes, drug users and prisoners (FRA, 2017).

National HIV Testing Strategy / Policy

HIV screening has been one of the strategic focus areas in the French HIV strategy and official city laboratories conduct about 80% of the 5 million HIV tests performed annually in France. The plan has been promoting a proactive strategy to support HIV / STI screening activities based on a “tripod for screening”:

1. Testing offered to all individuals independent of their risk exposure by a first resort health professional within the health care system (opt-out policy)
2. Targeted and regular screenings by peers in high-risk populations
3. Anonymous, free testing for HIV and other sexual transmitted infections in special testing and counselling centres

The strategy’s four population-based programmes have focused on homo- and transsexuals, migrants, sex workers and injecting drug users. Rapid diagnostic tests for orientation (Test Rapide d’Orientation Diagnostique; TROD) have been used to increase screening activities and earlier detection of HIV especially in these target groups. The provision of these rapid tests in community settings has helped to reach individuals with a high risk of exposure to HIV, who often had not previously used or had not had direct access to the health care system. An increase in the number of screening tests from 4.400 in 2011 to 56.500 in 2013 and the strong increase observed in the percentage of positive test results from 1.05% in 2012 to 8.6% in 2013 has shown the effectiveness of this approach (FRA, 2015).

French testing policies have also addressed the general public, especially through the general offer to test all people between 15 and 70 years of age for HIV at least once in their life whilst they are using the health care system. In addition several prevention campaigns have highlighted information about the necessity for more and earlier testing as well as the increasing diversity of testing opportunities being offered (INPES, 2010).

The French National Plan to combat HIV/AIDS and STIs relates to other national health plans including the plan against Hepatitis B and C, the plan against drug abuse and toxicomania or the youth health plan. HIV testing is also emphasized in the National Strategy for sexual health 2017 – 2030 (FRA, 2017).

Coordination of HIV Testing

The French Ministry of Social Affairs and Health, its General Directorate of Health (DGS) and an independent public body, the French National Authority for Health (HAS), are the main national actors responsible for HIV screening and testing activities. The French National AIDS & Viral Hepatitis Council, scientific institutions and a number of governmental and non-governmental organizations support their work. 17 Regional Health Agencies are in charge of developing and implementing HIV testing screening and testing strategies at the regional level. Santé Public France, the national agency for public health, is in charge of coordinating prevention and education activities and campaigns in all areas related to HIV / AIDS, including screening and testing.

Access

A range of HIV testing approaches are being used and are offered by various actors, especially aiming at reaching key populations on a regular basis for earlier infection detection.

HIV tests can be performed

- Initiated by a health care provider in various settings, e.g. clinical, for outpatients, in emergency departments or during preventive visits.
- Initiated by the person themselves; HIV testing is then usually carried out, free of charge in special community-based testing centres for HIV, viral hepatitis and sexually transmitted diseases (Centres gratuits d'information, de dépistage et de diagnostic, CeGIDD) as well as in some authorized family planning or mother and child centres.
- Anonymously, offered by a number of organizations using rapid diagnostic tests for orientation (TROD). This has proved to be highly effective in reaching persons who have a high-risk of an HIV infection, but haven't used the health system or other HIV testing services.
- By home sampling and self-testing with HIV self-test kits. Since 2015 such kits have been legally purchasable in France without prescription, but the costs are not covered by health insurance. (FRA, 2016)

HIV testing services for target populations (e.g. MSM, sex workers, IDUs, other marginalised groups) are offered in CeGIDDs, which are mainly located inside hospitals, and by mobile CeGIDD units. These mobile units run by health professionals and volunteers from HIV associations, offer counselling and testing (rapid and laboratory) for HIV and other sexually transmitted diseases during outreach activities focusing on areas with high transmission rates. The CeGIDD are run by the Regional Health Authorities and are co-financed by the Ministry of Health (CEGIDD, 2015).

Counselling

All testing centres for HIV and other sexually transmitted diseases offer pre- and post-test counselling services free of charge. The health insurance section as part of the national social insurance fund covers the costs for these services together with the Ministry of Health, provided as an annual fixed endowment by the 26 Regional Health Agencies.

Partner Notification

There is no legislative framework on partner notification, nor specialized professionals who are trained in this field. Research studies have been initiated to assess the feasibility and acceptability of partner notification interventions following the confirmation of an individual's positive test result (HAS, 2017a).

Process

The main HIV tests used in France are:

- **4th generation ELISA** (anti-HIV-1 & anti-HIV-2 antibodies, p24 antigen) followed by a Western blot to confirm a positive result
- **Rapid point-of-care tests** (HIV-1- and HIV-2-antibodies) followed by a 4th generation ELISA test to confirm a positive result
- **Self-tests** for use by lay persons at home (HIV-1- and HIV-2-antibodies) followed by a 4th generation ELISA test conducted by a health care professional to confirm a positive result

National HIV Testing Guidelines

The French HIV testing strategy and guidelines are based on two main documents published by the French National Authority for Health (Haute Autorité de Santé; HAS) at the request of the General Directorate of Health (DGS). While the first part focused on laboratory tests and algorithms, the second part has drawn attention to HIV screening strategies and programmes.

HIV infection screening in France - Laboratory tests and algorithms was published in 2008 and contained guidelines on HIV screening and laboratory diagnosis in adults and children over 18 months as well as guidelines and guidance on rapid screening tests. A two-stage strategy was used for the laboratory diagnosis of an HIV infection, in which a screening test was followed by a confirmation analysis on the same sample. If the confirmation analysis proved positive and consistent results were obtained from two separate samples, the HIV infection could be confirmed (HAS, 2008).

HIV infection screening in France – Screening strategies was published in 2009 (HAS, 2009). These strategies included a general recommendation for testing everyone between 15 and 70 years of age independent of any possible exposure to HIV at least once in their life when using the healthcare system. In addition strengthening testing programmes, targeting vulnerable populations such as MSM, IDUs and people originating from Sub-Saharan Africa and the Caribbean was recommended.

The French HIV infection screening strategy has now been evaluated and updated by HAS, including a comprehensive, scientific review and the

information concerning the involvement of multiple stakeholders (see also p.45). The results of this evaluation process have led to new recommendations (HAS, 2017a; HAS, 2017b).

A study on the impact of the primary care national policy on HIV screening in France (targeting all 15-70 year-olds) has shown a significant increase of HIV testing rates between 2006 and 2013, probably resulting in positive impacts on public and individual health outcomes (Sicsic et al., 2016). As incidence rates for vulnerable populations (MSM x 200, Migrants from Sub-Saharan Africa & Caribbean x 30-70, IDUs x 20) remain much higher than in the general heterosexual population, increasing the testing frequency and improving the recording of related data is highly recommended. This data would then be used for economic modelling and for the evaluation of testing approach efficiency.

About 40% of people living with HIV in France, mainly men and persons from key populations, are still being diagnosed at a late stage or with an advanced infection. These patients continue to contribute significantly to the transmission of HIV. Therefore the principal recommendations of the updated HIV screening strategy include:

- Increase the testing frequency in key populations
 - MSM every 3 months
 - IDUs every year
 - Migrants from high-prevalence areas, including Sub-Saharan Africa & Caribbean every year
- Continual testing of every citizen between 15 and 70 years of age at least once in their lifetime using an opt-out approach
- Strengthen screening activities in areas with higher incidence rates and suspected higher prevalence rates in key populations and for those men who rarely use the health system
- Offer HIV testing routinely in special circumstances e.g. when an STI, Hepatitis B or C or tuberculosis is diagnosed, during pregnancy, following rape, incarceration etc.
- Continue encouragement of voluntary HIV testing and counselling
- Considering the facilitation of HIV screening together with screening for Hepatitis B and C depending on risk factors present

Window Period

According to the French National Authority for Health a negative result of a 4th generation ELISA test indicates that the person is not infected with HIV only, if no risk of infection has been taken within a 6 week period prior to the test. A negative result of a rapid test or self-test can not be relied on, if a risk has been taken within a 3 month period prior to the test (HAS, 2015).

Costs

The average total costs for one HIV testing process, including an initial screening test, a laboratory test and counselling services is around 42 Euros (12-62 Euros). A Western blot test to confirm the result costs around 48 Euros. In general a screening test for HIV (ELISA 4th generation), prescribed by a health professional and conducted in a laboratory is free of charge for the individual and costs are covered by the national health insurance. This is also the case for testing in the CeGIDDs and for testing conducted by a number of non-governmental organizations. A single laboratory HIV test without a prescription, not covered by the health insurance, is about 19 Euros. Over-the-counter self-tests for HIV cost between 15-30 Euros and have to be paid privately.

As part of the 2017 evaluation of the French HIV/AIDS testing strategy a comprehensive economic modelling process has been conducted to identify the most cost-effective approach for HIV testing in the general population and in the high-risk target groups. Testing frequencies and related costs (in Euros / QALY; Table 5) were analysed and new recommendations have been published. Cost-effectiveness seems to be achieved by a testing

frequency of three months in MSM, and of one year for IDUs and migrants from high-prevalence countries. General population HIV screening offered once in a lifetime or even every 10 years appears to be cost-effective (HAS, 2017b).

Table 5: Summary of cost-effectiveness results (€/Quality adjusted life years (QALY)) of different HIV screening strategies: general population and key populations in France (HAS, 2017)

(Not viable = a more efficient and cost-effective alternative is already available)

Test frequency	General population	MSM	IDU	Migrants (from high-prevalence areas)
Once in a life	37.268	Not viable	Not viable	Not viable
Every 10 years	50.293	16.000	Not viable	24.667
Every 5 years	Not viable	19.940	20.152	Not viable
Every 3 years	121.647	Not viable	24.456	28.126
Annual	338.914	20.250	33.026	58.709
Every 6 months	Not viable	31.200	90.247	217.506
Every 3 months	1.254.199	40.340	190.857	234.467

Treatment, PEP and PrEP

Persons diagnosed with an HIV infection are eligible and encouraged to receive antiretroviral treatment free of charge, but not all migrants have been included in this policy. Post-exposure prophylaxis is available by prescription from specialist physicians and costs for PEP are covered by the national health insurance. In January 2016 France became the first country in Europe to offer free pre-exposure prophylaxis (PrEP). Prescriptions are only available from HIV specialist physicians in hospitals or at HIV testing centres (PrEPWatch, 2017).

Policy Evaluations

In March 2017 the French National Authority for Health (HAS) supported by a number of governmental and non-governmental organizations as well as a group of scientists published a comprehensive review of the French national HIV testing policies and guidelines and included a special cost effectiveness focus. New epidemiological data and data from the national health insurance database have been specifically analysed for this purpose, a systematic literature review has been carried out and an economic modelling project has been conducted (HAS, 2017a).

The indicators selected for the evaluation were

- Effectiveness in relation to the morbidity and mortality
- Acceptability
- Effectiveness of screening
- Number of positive tests
- Immuno-virologic status at the time of diagnosis
- Linkage to the healthcare system

People living with HIV in high-risk groups unaware of their infection mainly drive the HIV epidemic in France. Therefore a substantial increase of HIV testing programmes for these high-risk populations, adapted to the local contexts, has been strongly recommended. Several economic studies, including those used on the evaluation, have confirmed the effectiveness of the approach, where every adult (15-70 y.) is tested at least once in their lifetime for HIV.

Good Practice Examples

Since 2011 France has been successfully implementing a national, informal and anonymous HIV screening system, offered by non-governmental organizations using rapid diagnostic tests for orientation (TROD). This system has proved to be highly effective in reaching those persons at high-risk of an HIV infection, who are less likely to access the traditional healthcare system (e.g. MSM, drug addicts, sex workers, illegal migrants) (HAS, 2017a).

In 2015 the French authorities introduced the first HIV self-test in France. Several NGOs, such as the AIDES association, have shown their support of this measure by proving that these rapid screening tests can be administered safely and effectively even by non-health professionals. In addition a number of support initiatives were set up before the commercialisation of the first HIV self-test to inform target groups and the general public (e.g. phone platform, public communication campaigns, information/training for pharmacists, fact sheets for pharmacists) (SIDA, 2017).

Challenges

Some general practitioners and other health-care providers have not yet included the once-in-a-lifetime approach into their daily work routine. Further consultations, information campaigns and communication tools are under discussion to increase the acceptability of this approach. The implementation of the national HIV strategy and testing policies has been weakened due to the reorganization of the French healthcare system creating 17, largely autonomous Regional Health Authorities (ARS) in 2009 and by the decrease in public funding for NGOs since 2011. Strengthening the link between the HIV/STI offices at the national level with the ARS and between the ARS and the regional HIV coordinating structures, including NGOs, was recommended (Geffroy L, 2014).

1.2 GERMANY



The HIV situation in Germany can be described as a concentrated epidemic. In 2016 approximately 14% of an estimated 88.400 persons living with HIV were not aware of their HIV infection. 86% of those diagnosed received ART. The most affected population groups are MSM, migrants originating from countries with a high HIV prevalence and IDUs. More than 50% of all new infections were diagnosed in men who have sex with men and about 70-75 % of all people living with HIV in Germany belonged to this group (Table 6).

Table 6: HIV situation in Germany

HIV STATISTICS	Germany
General population (in Million) ¹	80.69
Persons living with HIV (2016) ²	88.400
% of PLHIV in the general population	0,1%
90 – 90 – 90 TARGETS³	2015
1 st 90: % of PLHIV knowing their status	85%
2 nd 90: % of PLHIV diagnosed and on ART	84%
3 rd 90: % of PLHIV, ART with viral suppression	93%
NEW DIAGNOSES (2016)	3419
New HIV diagnoses per 100.000 population	4.2
• Male	6.7
• Female	1.7
By mode of transmission	
• MSM	50.4%
• Heterosexual contact	25.3%
• Injecting drug use (IDU)	3.7%
• Other or undetermined	20.5%

Sources:

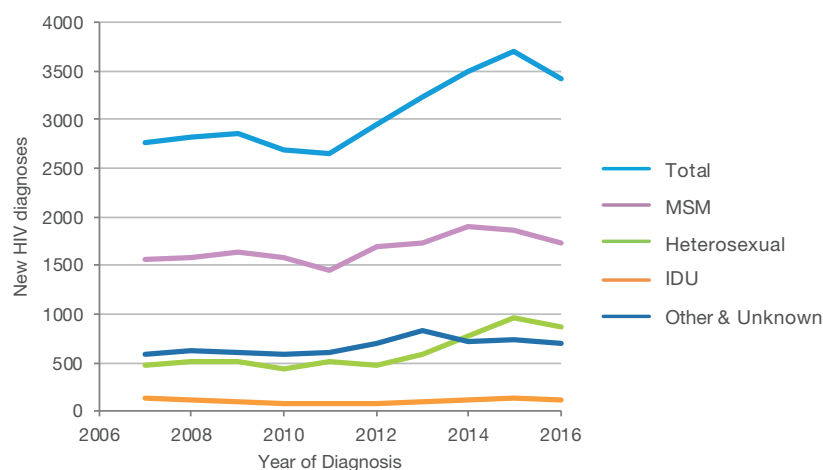
1 World Population Prospects, 2015 Revision, (UNDESA, 2015)

2 RKI, Epidemiologisches Bulletin 47/2017, (RKI, 2017)

3 Continuum of HIV care, (ECDC, 2017)

Between 2006 and 2012 the number of new HIV diagnoses in Germany was relatively stable, but the number increased to more than 3600 in 2015 (Figure 8). This increase was caused by two factors. Firstly there was an increase in HIV diagnosis in MSM and secondly more than 1.5 million immigrants have arrived in Germany since 2013, including large numbers from high HIV prevalence countries in Sub-Saharan Africa (RKI, 2016).

Figure 8: New HIV diagnoses, total and by mode of transmission, Germany, 2007-2016



As the number of new HIV infections has been increasing in recent years and as about 30% of those diagnosed have only been identified at an advanced stage of the infection (having either AIDS or a CD4 cell count $< 200 /\mu\text{l}$), the RKI estimates that there are even more people getting infected with HIV than are diagnosed every year. To achieve an earlier diagnosis of HIV infections, the RKI emphasizes the need for removing testing barriers for vulnerable groups and furthermore addressing those people living with HIV, who might be unaware of their risk of infection and transmission, e.g. heterosexual women with an undisclosed bisexual male partner (RKI, 2016).

The Robert Koch-Institute (RKI), the German national institute for epidemiology, publishes annual reports on the HIV situation in Germany. These cover a range of surveillance data, including information from infectious diseases and death registries and from pharmaceutical sales statistics to estimate the HIV / AIDS prevalence and incidence rates. There is no systematic data collected on the number of HIV tests conducted in Germany. An increase in the number of tests and a growing willingness to be tested among individuals from key populations has been observed (esp. in MSM). A 2013/2014 study with more than 15.000 men showed that 38.5% of them had an HIV test within a 12-month period before the interview. Another study showed that 64.1% of injecting drug users reported being tested for HIV in the 12 months prior to the study (ECDC, 2017c).

Source: HIV/AIDS Surveillance in Europe 2017 – 2016 data, (ECDC, 2017e);

As anonymous testing for HIV is common and not systematically reported, it is difficult to estimate the overall number of people tested in Germany. The Robert Koch-Institute and the Central Research Institute of Ambulatory Health Care in Germany therefore conducted a study using data collected through the statutory health insurance system to determine the number of people tested non-anonymously by practitioners in Germany. The annual number of people tested for HIV increased significantly from 865.918 in 2010 to 999.465 in 2015, indicating that on average 1.7% of statutory health insured people aged 15-74 were screened for HIV per year. 82.5% of these people were female and 17.5% men. This is due to the general HIV screening offer during pregnancy. In 0.3% of all cases a confirmatory test was conducted by the practitioners. The number of confirmatory tests decreased from 3.062 in 2010 to 2.605 in 2015. These results and the fact that the number of HIV diagnoses has been rising during the same time period, clearly indicate that many HIV diagnoses are made in other settings. Especially men who have sex with men appear to prefer anonymous and low-threshold testing sites (Hofmann, 2017).

National HIV strategy

Updating the 2005 **German HIV/AIDS strategy** (GER, 2005) the German Federal Government published a new **Integrated strategy for HIV, Hepatitis B and C and other sexually transmitted diseases** in 2016, which is based on a demand-orientated and cross-sectoral concept (GER, 2016).

Major principles of the strategy are

- Safeguarding sexual rights and the acceptance of diversity
- Self-determination of the individual
- Personal responsibility to respect and protect oneself and others
- Inclusion of self-help institutions, empowerment and participation

Main goals of the strategy are

- Creating an enabling environment to promote the acceptance of sexual orientations and different lifestyles
- Expanding needs-orientated services for populations at risk and those affected
- Developing integrated services addressing the different infections and making coordinated prevention, testing and care services available
- Promoting networking and cross-sectoral cooperation to reach people in their respective circumstances and to facilitate coordinated, high-quality services
- Generating and expanding strategic information and data to improve the planning and implementation of prevention, testing and treatment interventions (GER, 2016)

National HIV Prevention Activities

Since the 1980s a wide range of HIV prevention activities targeting the general population and high risk groups have led to a high level of knowledge regarding the transmission of HIV. However the Federal Government has identified a number of gaps that still need to be addressed using an integrated approach including prevention and information campaigns against other STIs. This includes the further expansion of demand-orientated services focusing on specific populations. Freely accessible educational media on HIV and STIs, quality-assured sexuality education and prevention services offered through social media are being used to reach the adolescent population. Education and information about effective protection and risk management strategies are continually offered to MSM through special knowledge portals, NGOs and gay advice agencies.

Special attention is also given to the migrant population by developing low-threshold, culture-sensitive information portals in different languages, offering culture-sensitive advice and care services, as well as by increasing the use of interpreters. To improve the response the Federal government is planning to adapt best practice examples from the countries of origin. Other target groups of focused HIV prevention activities include sex workers and their clients, transgender people and prisoners (GER, 2016).

The Federal Centre for Health Education (BZgA) has been involved in HIV/AIDS prevention activities since 1987 combining mass-media and personal communication measures specifically targeting different population groups. The primary goals of these activities such as the “Don’t give AIDS a chance”

campaign or the “Liebesleben” Internet platform are to “prevent the further spread of HIV and other STIs and to create and strengthen a social climate of solidarity with, and non-isolation of, affected person” (BZgA, 2017a). BZgA has also been working closely with Deutsche AIDS-Hilfe, an umbrella organization of more than 130 NGOs, offering a wide range of counselling and information services as well as trainings for services providers e.g. for acquiring intercultural communication and competencies in the field of HIV prevention (DAH, 2017b).

National HIV Testing Strategy / Policy

Germany does not have a special national strategy for HIV testing. The 2016 integrated strategy emphasizes the vital importance of testing services, closing the gap between prevention and care not only for HIV, but also for other sexually transmitted and blood-borne diseases (Hepatitis B and C, Syphilis, Gonorrhoea, Chlamydia, HPV). Furthermore it recommends that prevention and testing services should be embedded into a comprehensive range of cultural-sensitive counselling services, taking gender-related and psychosocial aspects into account. In general, an opt-in policy has been used.

Studies and surveys in Germany have indicated specific needs and approaches in relation to HIV and STI testing for MSM, IDUs, female sex workers and their clients, migrants, especially those arriving from a Sub-Saharan African country as well as inmates and staff of detention facilities. Adjustments in counselling and testing services and structures are presently paying special attention to these target groups. A variety of education and prevention programmes and campaigns have been addressing the general public, especially teenagers and young adults, in addition to offering immunisation (Hepatitis B, HPV) and screening services (Chlamydia for young women and HIV, Syphilis and Chlamydia testing for pregnant women).

The government has been planning to update and refine standards, recommendations and guidelines for testing of various infectious diseases. Studies are to be carried out to evaluate new testing procedures and technologies as well as to assess specific needs and approaches for

optimising high-risk group testing and diagnosis services. There will also be projects monitoring and evaluating target group-specific advice and testing service models. In addition information material will be made more widely available by medical societies and associations as well as by independent agencies aimed at improving the utilization of testing and treatment services developed and professional training (GER, 2016).

Coordination of HIV Testing

The Federal Ministry of Health is in charge of the overall coordination of the national HIV/AIDS strategy, including screening and testing regulation. Professional associations and societies develop testing guidelines. The Federal Ministry of Health and the regions (Länder) are coordinating their implementation as well as programmes and activities between national and regional agencies and departments and between sectors. In addition a national board including representatives from the Länder, professional associations and civil society has been built. The BZgA is responsible for providing information, developing educational material and implementing prevention campaigns for HIV and other STIs (BZgA, 2017b). Similar services for key populations are also offered by civil society organizations such as Deutsche AIDS-Hilfe (DAH, 2017a).

Access

Voluntary counselling and testing is a core aspect of the German HIV strategy. Germany has a wide range of service-providers offering HIV and STI testing. These services depend on the individual provider and on regional differences between the 16 federal states.

HIV and STI testing opportunities include:

- Anonymous advisory and testing services provided by the public health service
- Low-threshold advisory and testing services provided by non-governmental organisations and other independent agencies
- Testing in clinics and by general practitioners

Most of the testing centres are open for everyone, a few target specific groups only, e.g. MSM. These centres are run and financed mainly by non-governmental organizations.

Tests for home sampling and self-testing are not available in Germany for purchase by a private person. An online purchase from outside of Germany is possible, but customs authorities could withhold the delivery. However the Federal Ministry of Health is now considering the national accreditation of HIV rapid tests for use at home in the light of recognizing the promising results in other countries such as the UK, France and Australia (DÄ, 2017). Under the leadership of Münchner AIDS Hilfe a pilot study on home sampling will be launched in January 2018.

Counselling

All of the testing centres for HIV and other sexually transmitted diseases offer pre- and post-test counselling services free of charge to the individual. Costs for these services are covered either by the individual's health insurance, the public health service (when tested anonymously) or by non-governmental organisations and other independent agencies.

Partner Notification

Germany has neither a legislative framework on partner notification nor any specialized professionals who are specifically trained in this field. However advice on this issue has been offered routinely during post-test counselling services in the different testing sites.

Process

The main HIV tests used in Germany are:

- **4th generation ELISA** (anti-HIV-1 & anti-HIV-2 antibodies, p24 antigen) followed by an Immunoblot or NAT to confirm a positive or inconclusive result
- **Rapid point-of-care tests** (HIV-1- and HIV-2-antibodies) followed by a 4th generation ELISA test, Immunoblot or NAT to confirm a positive result

National HIV Testing Guidelines

Germany's HIV testing guidelines have been regularly updated by a joint commission of the German Association against Virus Diseases and the German Society of Virology in cooperation with the German AIDS society, a working group of physicians specialized in treating HIV patients (DAGNÄ) and the professional association of doctors for microbiology, virology and infectious disease epidemiology (BÄMI) (Rabenau et al., 2015). In 2015 the latest update was published with the overall goal of detecting the HIV infection as soon as possible after the transmission event, using the first sample taken (serum or plasma) in order to be able to start early treatment.

A new testing algorithm has also been developed and a stepwise approach has been used to get reliable confirmation of the HIV infection before the patient is informed. All positive results have to be reported to the Robert Koch Institute by anonymous reporting of laboratories. After a positive or inconclusive 4th generation screening test, an Immunoblot or Nucleic Acid Amplification Test (NAT) has to be used to confirm the HIV diagnosis. The primary sample (serum or plasma), which was used for the initial screening test, should be used for both tests to shorten the time between diagnosis and treatment. A NAT is recommended, if there is a negative Immunoblot result, despite a positive or inconclusive screening test. In the case that a NAT has been used as the primary tool for confirmation and the result has been inconclusive, an Immunoblot should be used. To ensure the validity of a NAT at least 1000 copies/ml need to be detected in order to use the result for the confirmation of an HIV diagnosis (Rabenau et al., 2015).

Window Period

Following the 2015 revision of the HIV guidelines the window period has been reduced to 6 weeks, if a 4th generation test has been used and the person tested has not been exposed to HIV within this period. For rapid tests, even if the p24-antigen could also be detected in this test, the window period remains at 12 weeks with no further HIV transmission risk taken during this period (Rabenau et al., 2015).

Costs

Costs for an HIV test vary between the different testing sites and the tests being used. The most commonly used antibody tests (ELISA and Western Blot) are free of charge for the individual in anonymous advisory and testing centers provided by the public health service, in clinics and at general practitioners. The public or private health insurances cover the costs in most circumstances. In some cases, e.g. when individuals are tested in private laboratories without a physician's prescription, the patients have to pay about € 20-30 for the test. HIV self-tests are not yet legally available in Germany, but can be ordered online, for about € 20-30 (HIV-Symptome, 2017).

Treatment, PEP and PrEP

In its 2015 guidelines the German AIDS society recommend starting antiretroviral therapy as soon as possible following the diagnosis and a detailed consultation with a specialized physician. In asymptomatic patients a wait-and-see approach could be discussed individually, always keeping the transmission risk in mind. Treatment costs have been covered by the health insurances (DAIG, 2015). The German AIDS society in collaboration with the Robert Koch-Institute and other organizations published guidelines for post-exposure prophylaxis in 2013. When indicated and prescribed by a physician, PEP has been covered by the health insurance (DAIG, 2013).

Following the approval by the European Medicines Agency physicians in German can prescribe pre-exposure prophylaxis (PrEP). About 2000 individuals are estimated to be using PrEP already, despite the fact that in most regions they have to cover the costs personally (about € 50 per month). Starting in 2018 costs for low-income patients will be covered in the Berlin area (Personal communication with a RKI representative).

Policy Evaluations

As Germany does not have a special national strategy for HIV testing, no specific evaluation has been conducted in this area. However the national HIV strategy has been updated on a regular basis, including some aspects concerning HIV testing.

Good Practice Examples

Germany has had very good experience with coordinated and supportive collaborations between governmental and non-governmental organizations for the development and implementation of HIV/AIDS prevention and testing strategies and services. For example, while the Federal Centre for Health Education (BZgA) has focused on the general population and the major target groups, the German Association of AIDS Self-Help Groups, an umbrella organization of more than 130 local AIDS groups and initiatives, has primarily targeted vulnerable populations and those most affected by HIV (GER, 2012).

Challenges

As Germany has been using an opt-in policy a person who wishes to be tested for HIV or another STI has to visit a physician or a physician-headed testing centre and also has to clearly indicate that they want to be tested (RKI, 2016). According to the Federal Ministry of Health patients (esp. young people, MSM, IDUs and prisoners) have often not been sufficiently informed about counselling, testing and treatment services. In addition these services were still unavailable in some regions with high-prevalence rates of STIs (GER, 2016).

Another increasing challenge has been the development and implementation of HIV testing policies and programmes for migrants, especially those arriving from high prevalence areas, especially Sub-Saharan African countries. The number of new HIV diagnosis in Germany has risen following the intake of more than 1.5 million immigrants in the past years. Many of these migrants arrived in Bavaria, one of the largest federal states in Germany, where they were routinely tested for HIV immediately after arrival. According to the national German Asylum Act, decisions concerning the choice of tests to be used are the responsibility of the individual federal states concerned. In this case the Bavarian health authorities decided against the recommendations from WHO, ECDC and the RKI. These organizations all recommend a cultural-sensitive approach, offering voluntary counselling and testing to asylum seekers, refugees and other migrants (RKI, 2016).

This example also demonstrates some of the structural challenges of Germany's health system. Although this is, in principle, under the jurisdiction of the federal states, it is actually based on a large number of relevant actors at the local, regional and national levels. Specific interventions like health care provision and HIV services in prisons have been highly dependent on these decentralised structures. Maintaining adequate HIV testing capacities, monitoring and evaluation and a systematic collection of HIV testing data at all levels therefore remains a major challenge in Germany (GER, 2012).

1.3 NETHERLANDS



The HIV situation in the Netherlands can be described as a concentrated epidemic with a low prevalence in the general population and a higher prevalence in specific populations (e.g. MSM, migrants from high-prevalence countries). The Netherlands have nearly achieved the UNAIDS 90-90-90 targets with about 816 new HIV diagnoses in 2015 (Table 7), showing a significant decline by almost 40% since 2008 (Figure 9) (SHM, 2017c).

Table 7: HIV situation in the Netherlands

HIV STATISTICS	Netherlands
General population (in Million) ¹	17.1
Persons living with HIV (2016) ²	22.900
% of PLHIV in the general population	0,1%
90 – 90 – 90 TARGETS³	2015
1 st 90: % of PLHIV knowing their status	88%
2 nd 90: % of PLHIV diagnosed and on ART	88%
3 rd 90: % of PLHIV, ART with viral suppression	93%
NEW DIAGNOSES (adj. for reporting delay)⁴	816
New HIV diagnoses per 100.000 population	4.4
• Male	7.6
• Female	1.2
By mode of transmission	
• MSM	68%
• Heterosexual contact	26%
• Injecting drug use (IDU)	0,1%
• Other or undetermined	7%

Sources:

1 World Population Prospects, 2016 Revision, (UNDESA, 2015)

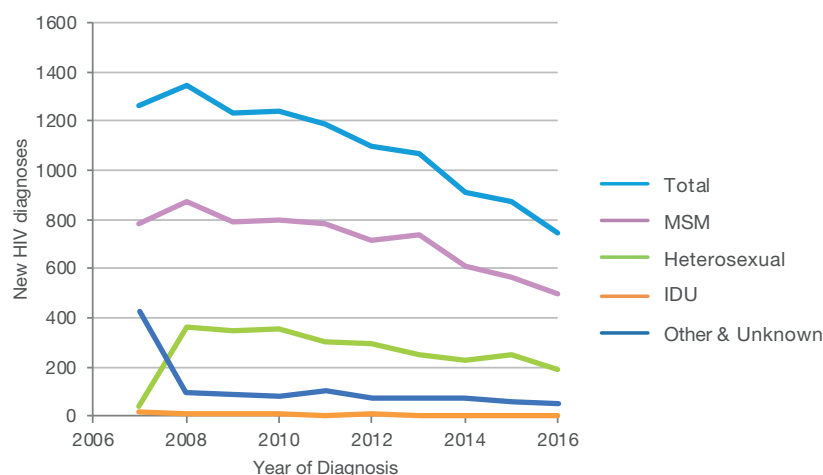
2 HIV/AIDS Surveillance in Europe 2017 – 2016 data, (ECDC, 2017e)

3 Continuum of HIV care, (ECDC, 2017)

4 Stichting Monitoring Report, 2017, (SHM, 2017c)

The main modes of HIV transmission in the Netherlands are through sex between men (68%) and heterosexual contacts (26%), transmission through injecting drug use appears to be extremely low. While the percentage of new infections among MSM has been decreasing over time, this group remains one of the high-risk groups in the Netherlands together with heterosexual migrants from high-prevalence countries (RIVM, 2017b).

Figure 9: New HIV diagnoses, total and by mode of transmission, Netherlands 2007-2016



Source: HIV/AIDS Surveillance in Europe 2017 – 2016 data, (ECDC, 2017e);

There is no legal regulation to report HIV infections in the Netherlands. Stichting HIV Monitoring (SHM), the Dutch HIV Monitoring Foundation, subsidized by the National Institute for Public Health and the Environment (RIVM), has been collecting coded data systematically from all registered HIV patients as part of routine healthcare for HIV. SHM has been working closely with all HIV treatment centres in the Netherlands to produce centre-specific reports and allowing HIV treatment centres to optimise their patient care. SHM data has also been used for the annual HIV monitoring report and for HIV-related research in the Netherlands and abroad (SHM, 2017a). SHM has also contributed to the biannual report on sexually transmitted infections, including HIV, in the Netherlands by RIVM (RIVM, 2017b).

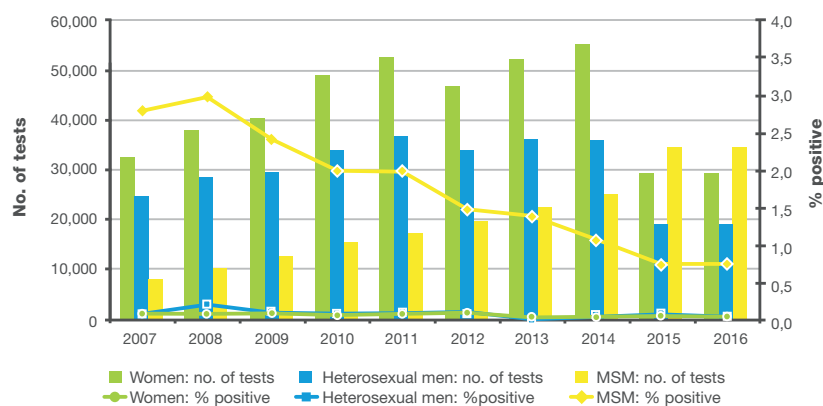
Late diagnosis and delayed linkage to treatment and care are still of concern in the Netherlands. A study, including all HIV positive patients in the Netherlands between January 1996 and June 2014, showed that 53% of patients, especially heterosexual men, those older than 50 years and immigrants from HIV endemic areas, first presented themselves at a late stage of their infection (de Coul et al., 2016). Another study, which included more than 300 patients newly diagnosed with HIV in one of the STI clinics, indicated that more than 30% were not linked to care within 4 weeks after diagnosis. This especially applied to vulnerable subpopulations (young, uninsured, ethnic minorities) (Van Veen et al., 2015).

As HIV is not a notifiable disease and as a wide range of stakeholders are involved in HIV testing activities in the Netherlands, no estimations can be made in relation to the overall number of HIV tests conducted. In a 2016 report RIVM reports that HIV testing rates seem to be increasing in certain

settings. In addition the proportion of patients, who had been diagnosed and treated earlier in their infection continues to increase, particularly amongst MSM (RIVM, 2016).

Data provided to the RIVM by a network of Centres of Sexual Health, shows an increasing number of HIV tests being conducted among MSM up to 2016 with MSM having the highest but declining positivity rates. The drop in HIV tests among heterosexual males and females since 2014 has been associated with a change in the inclusion criteria for HIV testing (low risk groups are no longer routinely tested) (Figure 10).

Figure 10: Total number of HIV tests and positivity rate of new HIV diagnoses by gender and sexual preference, centres for sexual health, the Netherlands, 2007-2016



Source: RIVM, Sexually transmitted infections, (RIVM, 2017b)

National HIV strategy

The first **Dutch National policy plan STI/HIV 2012 – 2016, “To renew and reinforce”** was published in December 2011. The plan was developed by the Centre for Infectious Diseases Control (CIb) of the National Institute for Public Health and the Environment (RIVM) in close collaboration with the Ministry of Health, Welfare and Sport, and many other stakeholders involved in HIV and STI control at the national and subnational level (NED, 2011). An update of the national policy plan is currently established by the CIb together with many stakeholders and will be published early in 2018. In this **New Action Plan STI, HIV and sexual health** an integral plan will be launched in which the need for a firm basis is emphasised, which addresses general sexual health and education as well as the need for surveillance and monitoring (of implementation of interventions).

Human rights aspects such as universal access to comprehensive prevention programmes, treatment, care and support are central to the HIV/AIDS policy in the Netherlands and the Dutch government has been placing these aspects into a larger framework of sexual health. The national note on health policy (Landelijke nota gezondheidsbeleid, 2011), has formed the basis for the current lifestyle policy, addressing multiple health issues, including sexual health and has also influenced the national STI/HIV plan.

The central principles of Dutch HIV/AIDS policy are to

- Emphasize the importance of primary prevention
- Improve the linkage between prevention and care
- Increase efforts to ensure low-threshold access to information, testing and treatment
- Underline the crucial contributions of different (non-) governmental stakeholders

In the national plan responsibilities and relations of these (non-) governmental stakeholders have been described to reduce overlap and gaps. These responsibilities have been divided mainly between risk groups to support tailor-made approaches based on the expertise of the respective organizations.

The following risk populations are identified in the national policy plan for STI/HIV:

- Young people
- Men who have sex with men (MSM)
- Migrants (primarily those from HIV-endemic countries)
- HIV-infected people

In addition special attention has been given to groups, which have been difficult to reach such as sex-workers, IDU's and people who belong to more than one key population (e.g. MSM/migrant)

National HIV Prevention Activities

Primary prevention and strengthening the linkage between prevention and care are two of the main principles of the Dutch national policy plan for STI/HIV. Information about safe sex practices and other opportunities to prevent STI/HIV infections are important components of the Dutch response and comprehensive sexuality education in schools has been obligatory since 2012. Targeted communication activities for specific groups such as MSM, migrants, sex workers and their clients, IDUs, youth and other vulnerable groups have been developed and implemented in close cooperation with NGOs.

The Centre for Infectious Diseases Control (CIb) of the National Institute for Public Health and the Environment (RIVM) has been conducting research and providing advice for policy-makers, researchers, local authorities and the general public in the field of HIV / STI prevention. Under the Public Health and Prevention Act (WCPV) the responsibility for the promotion and implementation of prevention activities lies with the municipal (town or city) council. Additionally, subsidised sexual health care facilities provide testing and treatment facilities. These have been working closely with a number of non-governmental organizations, developing activities for specific at risk-groups (RIVM, 2016).

Most NGOs receive funding from the national government for the coordination and implementation of HIV prevention programme and activities targeted at specific groups. The Rutgers, for example, focuses on sexual and reproductive health for young people.

The Netherlands Institute for Health Promotion and Disease Prevention (NIGZ) has been targeting ethnic minorities and young people and has been working in this area together with STI Aids Netherlands.

The AFAPAC Foundation, an organization of sub-Saharan Africans living in the Netherlands, has been focusing on the prevention of and care for HIV and other STIs in migrant communities. Mainline and the Netherlands Institute of Mental Health and Addiction (Trimbos Institute) have coordinated prevention programs for IDUs. HIV Vereniging Nederland, the advocacy group for people living with HIV, has also been involved in HIV/STI prevention activities (ILO, 2005).

SOA AIDS Nederland, a foundation and “think tank”, has been involved in a number of HIV/STI prevention activities and programmes, information and advocacy campaigns. It offers a wide range of information services for both professionals and the general public (SOAIDS, 2017a). Share-Net Netherlands, a Dutch network and knowledge platform on sexual and reproductive health and HIV, is involved in prevention activities nationally and internationally (SN, 2017).

National HIV Strategy / Policy for HIV Testing

The Netherlands currently does not have a specific strategy or policy for HIV testing, but the Dutch national policy plan for STI/HIV has been addressing many related aspects. The promotion of HIV testing was considered to be of great importance for HIV prevention and an “active testing policy” has been applied in the Netherlands since 2002. This has included antenatal screening for pregnant women and the integration of testing aspects into the STI/HIV-protocol for GPs, encouraging them to offer HIV and STI tests to people from high-risk groups and to those who come from high-prevalence countries (RIVM, 2016).

In 2009 a specific regulation (Aanvullende Seksuele Gezondheidszorg (ASG)) was introduced to provide low-threshold and free of charge STI/HIV testing and care for high-risk groups at Centres of Sexual Health (RIVM, 2011). The National Institute for Public Health and the Environment (RIVM) has been in charge of developing, updating and distributing guidelines on HIV prevention, testing and treatment (RIVM, 2014c).

SOA AIDS Nederland has been deeply involved in developing HIV and STI policies in the Netherlands. A comprehensive study on proactive HIV testing strategies in primary care and other healthcare settings in the Netherlands, concluded that HIV indicator condition-guided testing by general practitioners was the key to a more proactive HIV testing approach (Joore, 2017). Taking the results of this study together with the existing focus on high-risk groups into account, SOA AIDS Netherlands has proposed two new additional testing approaches. GPs should offer HIV testing to patients with HIV indicator

diseases and they should also routinely offer HIV testing to all patients living in areas where HIV prevalence is higher than 2 per 1000 population. By using these two approaches the HIV tests would no longer be directly linked to sexual behavior or ethnicity (SOAIDS, 2017a).

Coordination of HIV Testing

The Ministry of Health, Welfare and Sport bears the main responsibility for HIV/AIDS and STI policies in the Netherlands. The Centre for Infectious Diseases Control of the National Institute for Public Health and the Environment coordinates policy development, including the development and implementation of prevention and testing activities in this area. Municipal authorities are legally co-responsible for STI/HIV-related prevention, testing and care. These tasks are usually conducted by the municipal health services (GGD), which receive national subsidies in order to install and run the Centres for Sexual Health (ASG). A wide range of governmental and non-governmental organizations, such as Stichting HIV Monitoring and SOA AIDS Netherlands have also been involved in HIV testing activities. In addition to regular meetings the “STI and sexual health platform”, has organized quarterly meetings, providing opportunities for interaction between the stakeholders (RIVM, 2016).

Access

Testing for HIV and other STIs is available to all throughout the Netherlands. Testing costs are reimbursed by mandatory health insurances, but all patients need to pay the first 385 Euros of their annual healthcare costs privately.

Testing opportunities are offered in a range of facilities:

- General practitioner's offices (where about 70% get their first HIV test)
- Municipal healthcare services and STI clinics (30%; testing only for risk groups, mainly used by MSM)
- Hospitals
- Non-governmental organizations (rapid tests under clinical supervision)
- Online services for risk groups
- Commercial services connected to accredited laboratories

(SHM, 2017b; RIVM, 2017b)

The STI clinics are targeted towards a high-risk population. Special GP centres, supported by STI clinics, have been established for asylum seekers. While STI clinics are subsidised through RIVM, healthcare costs for asylum seekers are covered by the Ministry of Health, Welfare and Sport.

In a pilot project HIV self-tests have been made available for purchase through the Internet. During the 2015 HIV testing week an online campaign motivating MSM and migrants was launched attracting more than 34.000 visitors to the campaign's website (www.time2test.nl). During the campaign phase an oral fluid-based test (OraSure) could be ordered for free together with a manual, online instructions and counselling services. Preliminary results of the study

linked to the campaign showed that almost 700 people ordered 935 tests and target groups were reached (HIVST, 2016).

Counselling

HIV and STI counselling services are offered by specially trained nurses and specialized doctors for free at STI clinics. These services complement the counselling services provided in the regular health care services (GP's office or hospitals) and HIV testing is performed here on an opt-out basis. The costs for these services are covered by the national health insurance and by subsidies from the national government (RIVM, 2016).

Several NGOs, for example the HIV Vereniging, also offer counselling services. SOA AIDS Netherlands offers a new, anonymous, fully automated advisory application for HIV testing. A computer program generates questions according to the user's responses simulating the usual kind of dialogue between a GP or an advisor at a STI clinic and a patient. The program offers appropriate advice on risks and testing opportunities, including self-testing options (SOAIDS, 2017b). SOA AIDS Netherlands is also using motivational counselling methods conducted by specially trained HIV/STI counsellors (SOAIDS, 2016).

Partner Notification

Partner notification is considered to be essential to test and treat the individuals concerned and to prevent the further spread of STI or HIV infection. It has been estimated that about one third of all STIs in the Netherlands were detected following the notification of a partner either by the infected person or a specially trained STI nurse at the healthcare centre where the infection was diagnosed. RIVM has examined the existing partner notification mechanisms in Dutch STI centers. Tracing of often anonymous and multiple partners of MSM continues to be very difficult. While only 46% of partners of MSM with an STI could be traced, 87% of partners of heterosexual women and 63% of partners of heterosexual men have been found and notified. A further problem is the limited time available to STI nurses for counselling and discussions on partner notification. Special courses for STI nurses are therefore being offered (RIVM, 2015).

The municipal healthcare services, STI clinics, SOA AIDS Netherlands and the College of General Practitioners have developed a special online tool to improve partner notification services in the Netherlands. A wide range of information is offered together with a web-based opportunity of notifying partners via Email or SMS including important information. This can also be done anonymously (PW, 2017).

Process

HIV testing in the STI clinics within the municipal health care services is based on an opt-out system. In other settings (GPs, hospitals) an opt-in system is used.

The main HIV tests used in the Netherlands are (RIVM, 2014c):

- **4th generation ELISA** (anti-HIV-1 & anti-HIV-2 antibodies, p24 antigen) followed by an Immunoblot to confirm positive results
- **Combined rapid point-of-care tests** (HIV-1- & HIV-2-antibodies plus p24 antigen) followed by 4th generation ELISA and an Immunoblot to confirm positive results

National HIV Testing Guidelines

The Coordination Centre for Infectious Diseases Control (LCI) at the National Institute for Public Health and the Environment is responsible for the national guidelines on HIV and other STIs. These have been continuously updated whenever indicated. These guidelines are binding and the Dutch Health Inspectorate has been monitoring their implementation and the quality of services provided (RIVM, 2014c).

The Dutch General Practitioner's Society has published clinical standards for sexually transmitted diseases, including HIV, which has also been updated on a regular basis (NHG, 2013). The Dutch Association of HIV-Treating Physicians (NVHB) publishes HIV treatment guidelines, which are reviewed annually and contain extensive information (NVHB, 2017).

Window Period

The Dutch GP's society recommends using a 4th generation ELISA test 3 months after taking a potential risk or earlier, if indicated by a physician. In this case and if the result is negative, another test should be taken at 3 months following the risk-taking event. If a rapid test is being used a 4th generation ELISA test is required to confirm a positive result. If a rapid test is negative, it should be repeated 3 months after the last risk-taking event (NHG, 2013).

Costs

HIV testing is available and free of charge for individuals from high-risk groups (e.g. MSM, migrants) at STI clinics. In general, the national health insurance system covers the costs for testing and treatment of HIV and other communicable diseases. However every patient has to pay the first 385 Euros of his/her healthcare costs annually. This implies that individuals, who are not from a high-risk group, might have to pay for an HIV or STI test (GNP+, 2017a). Due to the decentralised system involving many stakeholders, it is impossible to estimate the average price for an HIV test and the related laboratory procedure costs. Rapid tests cost about 5 Euros and a commercial laboratory has been offering HIV tests for 39-59 Euros (CheckU, 2017).

Treatment, PEP and PrEP

Following positive HIV tests all patients are referred to one of the nationwide 27 HIV treatment centres to initiate treatment, further counselling and care as soon as possible after the diagnosis has been made.

HIV treatment is available for all patients covered by the national health insurance system. Reimbursements for healthcare insurance costs for individuals with limited financial resources and asylum seekers are collectively organised (RIVM, 2016).

Post-exposure prophylaxis (PEP) is available in some STI clinics and in infectious diseases departments of hospitals, but availability differs between regions. Specially trained physicians make risk assessments to discuss the necessity for PEP (SOAIDS, 2017c).

Pre-exposure prophylaxis (PrEP) is registered in the Netherlands, but currently only available within a pilot study in Amsterdam. Based on a professional guideline on the risk of HIV and sexual behaviour healthcare providers determine the patient's eligibility to use PrEP. The costs for PrEP and associated healthcare costs are high and not covered by the national health insurance (RIVM, 2017a).

A mathematical modelling study, based on the HIV epidemic in the Netherlands, found that daily PrEP would be cost-effective even at current drug prices if it were targeted at gay men with a high risk of an HIV infection (Nichols et al.). The health council currently deliberates whether PrEP should be made eligible for refunding by health care insurance.

Policy Evaluations

The Dutch Ministry of Health is responsible for monitoring and evaluating the HIV/AIDS policy and programmatic frameworks. Key responsibilities providing information for the policy development process, e.g. surveillance activities, are coordinated by the RIVM. NGOs contribute to the Dutch monitoring and evaluation system through research, surveillance and evaluations in their respective areas of work and by suggesting possible policy solutions. Specific evaluations of organisations or stakeholders have been conducted regularly to assess the suitability of the individual programmes or activities. Recently an evaluation was performed to assess the functioning of the Stichting HIV Monitoring (SHM) system (RIVM, 2014b). In addition a midterm review of the plan and evaluation of the STI-clinic subsidies was conducted. The STI-clinic system, offering low-threshold access for people at risk of an HIV or STI infection, has proved to be an efficient addition to the existing primary care system. Following the evaluation a few adjustments were made, for example, a new financial ceiling for the programme has been imposed to keep the increasing costs under control (RIVM, 2014a).

Good Practice Examples

Over the past decade both low threshold access to STI clinics, offering free HIV and STI testing for designated risk groups, and awareness campaigns targeting these groups, have led to the growing number of HIV tests conducted. In addition the commitment and contributions of a range of national and local NGOs engaging in constructive dialogue on a regular basis has successfully fostered an enabling environment. RIVM has been working in close collaboration with these NGOs and HIV patient organizations, some of which have also been receiving national funding.

Target groups have increasingly been addressed and informed through online activities. These have included, for example, tailored websites to provide information about sexual health, HIV and other STIs as well as (online) testing opportunities for young people, and MSM or reaching out to special migrant groups using existing online communities (e.g. Antillean and Moroccan youth) (RIVM, 2016).

According to UNAIDS, Amsterdam has already reached the international UN 90-90-90 targets. This is partly due to the unique, ground-breaking work of the H-TEAM (HIV Transmission Elimination AMsterdam), which have combined various innovative interventions by promoting prevention, earlier HIV testing and immediate access to ART. The H-TEAM has been following a city-focused approach to the HIV epidemic, working closely with various other large cities, but has also tried to ensure their campaigns reach a nationwide audience as well. The H-Team has also been very much involved in the AMPREP project, a pilot study to learn more about the effectiveness and responses to PrEP prescription for MSM and transgender people at high risk of an infection (HTEAM, 2017).

Challenges

As an estimated 12% of PLHIV have not yet been diagnosed, maintaining activities and using new approaches, such as community-based testing and outreach activities to stimulate testing among high-risk groups, are considered to be of great importance. This especially applies to the “hard-to-reach groups”, e.g. MSM within migrant communities.

As HIV is not a notifiable disease in the Netherlands, epidemiological surveillance is more challenging there than in other countries. The national authorities have had to work closely with NGOs to obtain required data and information. This also applies to the interaction between public health professionals and GP's. As a large number of patients with a suspected HIV or STI infection have their first contact with a GP, it is essential that health professionals are well-informed about testing opportunities, counselling services and partner notification programmes (RIVM, 2016).

The costs for providing low-threshold access to STI/HIV testing and treatment for high-risk groups in STI clinics under the ASG regulation have been increasing in recent years. Following an evaluation of this approach a financial ceiling has been imposed and certain risk groups have been excluded from the programme (e.g. clients of sex workers with a limited number of partners within 6 months prior to the consultation) (RIVM, 2014a).

1.4 PORTUGAL



The HIV situation in Portugal can be described as a concentrated epidemic with about 1030 new HIV infections per year (Figure 11) and about 0.57% of the population are living with HIV (Table 8). In 2015 about 30% of persons living with HIV in Portugal were not aware of their serostatus, but more than 78% of those diagnosed with HIV were receiving ART.

Table 8: HIV situation in Portugal

HIV STATISTICS	Portugal
General population (in Million) ¹	10.35
Persons living with HIV (2016) ^{2*}	59.365
% of PLHIV in the general population	0.57%
90 – 90 – 90 TARGETS³	2014
1 st 90: % of PLHIV knowing their status	70%
2 nd 90: % of PLHIV diagnosed and on ART	67%
3 rd 90: % of PLHIV, ART with viral suppression	78%
NEW DIAGNOSES²	1030
New HIV diagnoses per 100.000 population	11.5
• Male	15.0
• Female	5.5
By mode of transmission (n=984)	
• MSM	35.6%
• Heterosexual contact	57.1%
• Injecting drug use (IDU)	2.8%
• Other or undetermined	4.5%

Sources:

1 World Population Prospects, 2015 Revision, (UNDESA, 2015)

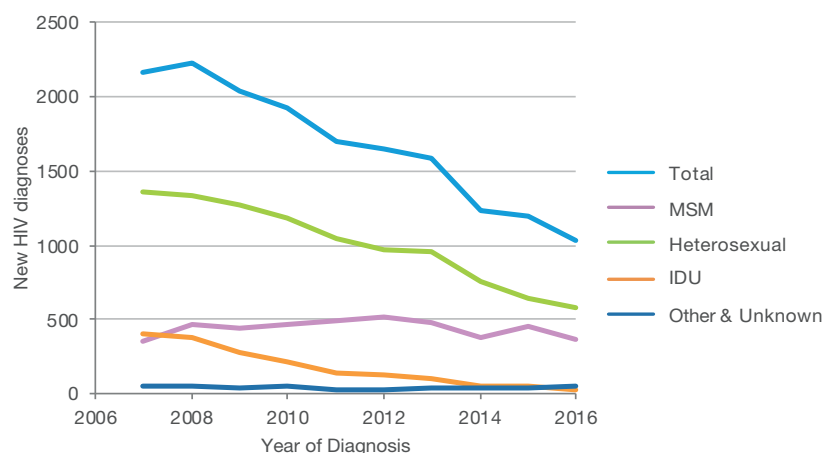
2 Portugal: Infecção VIH e SIDA: a situação em Portugal a 31 de dezembro de 2016;

*PLHIV data currently being reviewed

3 Continuum of HIV care, (ECDC, 2017)

The main modes of HIV transmission in Portugal are through heterosexual contacts (57.1%) and through sex between men (35.6%). Transmission through injecting drug use is now relatively low (2.8%) following a steep decrease within the last decade. While the number of new infections among heterosexuals has been gradually decreasing since 2007, the number of infections among men who have sex with men has been relatively stable. In 2016, the 68.4% of new cases occurred in individuals born in Portugal, aged ≥ 15 , (978 with available data) (POR, 2017).

Figure 11: New HIV diagnoses, total and by mode of transmission, Portugal 2007-2016



Source: HIV/AIDS Surveillance in Europe 2017 – 2016 data, (ECDC, 2017e);

The decrease in the overall number of new HIV diagnoses by almost 64% between 1999 and 2015 can be attributed to better access to more effective treatment opportunities and new approaches targeted at IDUs, including the decriminalization of the use of illegal substances and programmes for risk reduction and damage minimization (e.g. needle exchange and opiate replacement programmes). More than 70% of all new HIV diagnoses were made in three major districts: Lisbon, Porto and Setúbal (DGS, 2017b).

In Portugal physicians have to report all new HIV infections to the national surveillance centre at the National Institute of Health (INSA) following a diagnosis and whenever there is a change in the infection status (e.g. appearance of AIDS symptoms, death) (INSA, 2016). The Directorate General of Health (DGS) has implemented a HIV / AIDS electronic monitoring system (SI.VIDA) to improve surveillance, testing, treatment and care in this field. All major hospitals in Portugal are now connected to the SI.VIDA system, a hospital-based software designed to improve the clinical and epidemiological monitoring of people living with HIV in Portugal. These patients are closely followed-up on a regular basis (POR, 2012).

Studies are being conducted on, for example, risk factors for HIV and other STIs among MSM and immigrant communities in close cooperation with non-governmental organizations (GAT, AJPAS and Ser +) and using data from the SI.VIDA-System. Initial results highlight the importance of continuing investments in initiatives promoting behavior reduction and HIV testing, especially in the immigrant population (DGS, 2017b).

In 2016 the majority of newly diagnosed HIV patients was asymptomatic (65.2%) and a concurrent AIDS diagnosis occurred in 17.7% of cases. 55% of individuals presented late (CD4 count < 350 cells/mm³) and 35.5% with an advanced diseases (< 200 cells/mm³). These results and the fact that a high proportion of new HIV diagnoses occur in young people with a newly acquired infection are matters of concern and highlight the need for more effective and innovative prevention strategies and diffusion of prevention messages (POR, 2017).

In 2016 the number of rapid HIV tests performed at the primary health care level increased by 86.2% in comparison to the previous year (3980 vs. 2138), with 0.8% reactive results. In contrast to this, the Centers for HIV Counseling and Early Detection (CAD), which offer anonymous rapid testing, have reported an ongoing decrease in the number of tests performed in recent years (from 23.968 in 2010 to 10.916 tests in 2016). However an increase in the proportion of reactive cases from 1 to 1.6% has also been observed (DGS, 2017b). These trends can be explained mainly by two changes. Firstly, since NGOs began offering HIV rapid diagnostic tests to key population groups in 2010, testing has shifted towards these community-based organizations (at least in larger cities). In addition, the HIV testing clinical guidelines were updated in 2014. These recommended the use of rapid diagnostic tests to attain earlier diagnoses. These recommendations also applied to the primary health care sector (DGS, 2016b).

National HIV strategy

In its **National HIV / AIDS Prevention and Control Programme 2012-2016** the Portuguese Directorate General of Health emphasized the importance of clear guidance and an effective coordination in the response to the epidemic, including prevention strategies, good clinical practice and social support. The response to HIV / AIDS has been closely linked to the fight against other STIs, viral hepatitis and tuberculosis, ensuring a concerted multisectoral involvement, promoting behaviour and attitude change and reducing stigma and social discrimination (POR, 2011).

The vision of the **National Programme to Prevent and Control HIV infection, AIDS and Tuberculosis 2017 - 2020** is to reduce vulnerability and to transform Portugal into a country without HIV infection and tuberculosis. The programme is emphasized as a national health priority in Portugal's National Health Plan. It has been based on a human-rights approach and was developed through a multisectoral consultation process (DGS, 2017b).

The main goals of the national programme are (by 2020)

1. To achieve the 90-90-90 targets set by UNAIDS
2. To keep the rate of new HIV infections in new-borns below 50 cases / 100.000 live births and the vertical transmission below 2%
3. To reduce TB incidence to 15 / 100.000 population
4. To achieve therapeutic success in 90% of TB cases
5. To identify 90% of TB patients with an HIV infection

Main areas of work include:

- Informing communities about the risk of transmission of HIV, TB and other STIs and about prevention opportunities
- Strengthening and increasing the public health approach, including social development and poverty reduction, health promotion, and prevention activities
- Promoting community-based initiatives, focusing on vulnerable populations and those at higher risk of infection
- Increasing the frequency of screening tests and improving linkage to treatment and care, including monitoring of the clinical management and of patient's compliance
- Managing and reducing TB by developing and implementing effective, efficient and sustainable strategies.

To achieve the goals closer collaboration is being encouraged between the government, health professionals, researchers, civil society and communities of people infected and affected by HIV, TB and other co-infections.

National HIV Prevention Activities

The Portuguese government has emphasized the need to increase and improve prevention activities in the field of HIV, its sexually and parenteral transmitted co-infections as well as TB. The **National Programme to Prevent and Control HIV infection, AIDS and Tuberculosis 2017 - 2020** focuses on reducing the risk of infection in the general population and especially in target populations like MSM, IDUs, migrants, sex workers and pregnant women. The programme has been using awareness and information campaigns (e.g. on transmission risks, condom use, needle exchange programmes etc.), offering counselling services to support individuals in their decision-making and promoting HIV testing opportunities (DGS, 2017b).

In 2016 HIV prevention activities focused on information campaigns, the continuity and expansion of needle exchange and distribution programme (including in pharmacies) as well as the distribution of male condoms, which increased by 96.8% between 2012 (2.4 million) and 2016 (4.7 million) (DGS, 2017b). Almost 75% of all HIV infections in Portugal were diagnosed in the urban and suburban areas of Lisbon, Porto and Setúbal and most of the prevention activities have been conducted in these areas (INSA, 2016). In May 2017 the cities of Lisbon, Porto and Cascais signed the Paris Declaration on ending the AIDS epidemic in cities by establishing local strategies to remove barriers to accessing HIV services, eliminating discrimination and by closing the prevention and treatment gaps (UNAIDS, 2017a).

The **National Programme to Prevent and Control HIV infection, AIDS and Tuberculosis 2017 - 2020** sought to generate knowledge in specific areas considered a priority, promoting the studies “Immigrants: HIV and other sexually transmitted infections” and “HIV Infection: Study of Men who have Sex with Men: risk factors and new trajectories of HIV”. The Institute of Hygiene and Tropical Medicine developed the first study at the request of the programme and with the participation of three non-governmental organizations (GAT, AJPAS and Ser+). Key findings point to the importance of continuing to invest in initiatives that promote the reduction of risk behaviours and HIV testing of immigrants as a key-population group (DGS, 2015).

The second study was developed by a research team of the Institute of Sociology of the University of Porto and the Center for Research and Studies in Sociology of the Lisbon University Institute. This study was aiming at identifying the determinants and risk factors of HIV infection among MSM in Portugal, in particular among the younger age groups (up to 34 years), in order to inform decision-making and guide the intervention strategies. Results show that there is a strong association between the adoption of risk behaviours and the sense of confidence in relation to medical progress in the field of management and treatment of HIV infection (DGS, 2016a).

A special focus has been given to the early detection of HIV infections, especially in vulnerable populations with a high risk of transmission (e.g. IDUs, MSM, prisoners, ethnic minorities and migrants from high-prevalence countries). A range of projects have been developed for vulnerable populations, funded by the National Programme and led by 17 NGOs, such as the Grupo de Ativistas em Tratamentos (GAT). The community screening network (Rede de Rastreio Comunitária) which provides an early detection system for HIV, hepatitis B and C as well as syphilis and the mobile screening units which reach out to migrants, IDUs, MSM and sex workers (e.g. MOVE-SE in Setúbal district) are examples of these projects (GAT, 2017a).

As part of its campaign “Prevent, Diagnose and Treat – HIV and AIDS” the National Programme carried out three training sessions for health journalists between April and June 2016. These sessions covered information on the evolution of HIV epidemic in Portugal, prevention and treatment activities as well as on efficacy, costs and innovation in this area (DGS, 2017b).

National HIV Strategy / Policy For HIV Testing

National policies for HIV testing have been included in the **National Programme to Prevent and Control HIV infection, AIDS and Tuberculosis 2017 - 2020**. The key objectives are to raise awareness about the importance of knowing the personal HIV status and to ensure universal access to HIV screening tests in formal and informal health structures. In addition, this programme prioritizes both achieving earlier diagnoses of HIV infections and improving linkage to care. The main goals in 2017 have been to increase the number of rapid tests performed in the network of centers for HIV counselling and early detection, groups of health centres and community-based structures by 15% and to publish special recommendations for HIV testing in informal settings (DGS, 2017b).

Ensuring universal access to HIV testing was a general objective of the **National HIV / AIDS Prevention and Control Programme 2012-2016**. Specific objectives were:

1. Establishing a national network of HIV infection detection centers including governmental structures and NGOs
2. Ensuring access to testing, in formal and informal, community-based health structures, with counselling and referral to care within a week
3. Promoting the realization of testing opportunities for vulnerable groups, particularly IDUs, sex workers and MSM
4. Promoting opportunities to increase earlier detection of HIV infections
5. Increasing the proportion of cases detected with a CD4-cell count of more than 350/mm³
6. Promoting tracing of contacts
7. Promoting the combined detection of HIV, other STIs, viral hepatitis and TB by increasing the capacity of testing centres

The availability of anonymous testing opportunities, offering voluntary or provider-initiated counselling and testing services free for all who want to know their HIV status continues to be of high priority for the Portuguese government (POR, 2011).

Coordination of HIV Testing

The Ministry of Health, the Directorate General of Health and the National Programme for HIV/AIDS and Tuberculosis are leading the Portuguese response to the HIV epidemic. The National Institute of Health Dr. Ricardo Jorge (INSA), professional associations, regional health administrations, the Labour Platform against HIV /AIDS and a number of NGOs are also among the key stakeholders involved in this field (SNS, 2017b). The Portuguese government has been working closely with a range of NGOs and has been financing a number of their projects (e.g. in 2016, € 2.58 million for 28 projects, including testing projects) (DGS, 2017b).

The Portuguese Civil Society National Forum for HIV Aids, Tuberculosis and Viral Hepatitis includes a wide range of organization, e.g., patient's organizations, organizations providing counselling and testing services, faith-based organizations, and members from the network on sex workers among others. This forum has been included in the development and implementation of national HIV testing programmes and initiatives and its member organizations have been partially funded by the national government (SNS, 2017a).

Access

Various actors, aiming at reaching key populations for earlier infection detection, have been using different HIV testing approaches.

In Portugal HIV tests can be performed in the following settings:

- Laboratory tests can be prescribed by medical doctors in primary health care centers, hospitals and all other health facilities within the National Health System, some also offer rapid tests. Indicator-condition testing is being promoted.
- Network of centers for HIV counselling and early detection (Centros de Aconselhamento e Detecção Precoce do VIH, CAD), offering anonymous, voluntary, rapid testing in 14 of the 18 districts.
- Community-based organizations offering rapid testing services, targeting mostly key population groups.
- Addiction treatment structures are encouraged to offer rapid tests, but availability still varies
- Prison inmates are tested for HIV at entry and then at least once per year (ECDC, 2016a).

Self-testing for HIV is prohibited by law in Portugal. The in vitro devices for the detection of HIV1 and HIV2 antibodies should be used under the supervision of a professional in the clinical laboratory area. This also applies to other infectious diseases like hepatitis B and C, blood grouping and genetic screening (HIVST, 2017a). However HIV home testing is currently under discussion and a home sampling pilot project is presently being carried out (personal communication).

Since the introduction of rapid tests community-based organizations have become key partners to national health services in the area of testing for HIV / AIDS, viral hepatitis and other STIs. Medical professionals and trained lay people deliver community-based testing services with most NGOs working under the umbrella of a GAT led project (Rede de Rastreio Comunitária), which has established a community based screening network. GAT has been working in a partnership with the Institute of Public Health of the University of Porto (ISPUP) and the Immunohemotherapy Service of São João Hospital, aiming at implementing a service for early diagnosis of HIV, HBV, HCV and syphilis and at collecting and reporting data for epidemiologic surveillance of hard-to-reach populations. The project has been complementing services provided by the formal health system ensuring appropriate linkage to care (RDR, 2017).

Target population centers have been opened specifically for MSM (e.g. CheckpointLX in Lisbon and Abraço Centro Comunitário in Porto) and IDUs, other testing projects have at least a partial focus on migrants and sex workers. These centers are mainly run by non-governmental, community-based organizations and are mostly funded or co-funded by the National Programme for HIV, AIDS and Tuberculosis or the National Service for Drugs and Drug addiction.

Counselling

All HIV testing centers in Portugal offer counselling services. In the formal structures of the national health system health professionals or psychologists are usually in charge of counselling. In community-based testing facilities both health professionals and trained lay workers provide counselling and testing services in addition to prevention materials and referrals to speciality centers in cases of reactive test results. The majority of NGOs offer the possibility of a counsellor accompanying the person to at least their first medical appointment. The National Health Service covers the costs for counselling service in public structures and also partially for the non-governmental organization providers. NGOs can apply for public funding through a grant procedure annually.

Partner Notification

Portugal does not have national guidelines for partner notification following an HIV diagnosis. However advice on this issue is offered routinely during post-test counselling services in the different testing sites. GAT and CheckpointLX have developed the CheckMe application for mobile phones, including information on HIV and STIs, maps with counselling and testing centers as well as an option for anonymous notification of partners (GAT, 2017b).

Process

The main HIV tests used in Portugal are:

- **3rd or 4th generation ELISA** (anti-HIV-1 & anti-HIV-2 antibodies, p24 antigen)
- **Combined rapid point-of-care tests** (HIV-1- & HIV-2-antibodies plus p24 antigen) followed by 3rd or 4th generation ELISA and an Immunoblot to confirm positive results

Laboratory tests are mainly used in formal healthcare structures and prisons. Rapid tests, often still of the 3rd generation, are used in community settings and CAD testing centers. A switch to 4th generation rapid tests is currently planned for CheckpointLX in Lisbon.

National HIV Testing Guidelines

The Directorate General of Health published national guidelines for the **Diagnosis and Laboratory Screening for Human Immunodeficiency Virus (HIV)** in 2012, with the latest update in 2014. In Portugal an opt-out strategy is now used. Laboratory testing for HIV has been recommended for all individuals between 18 and 64 years when accessing the health system at least once. In addition a non-reactive test should be repeated in different subpopulations regardless of age (DGS, 2014):

- a. Persons with signs and symptoms indicating a possible HIV infection
- b. Persons diagnosed with an STI
- c. Sexual partners of persons diagnosed with HIV
- d. MSM (at least annually)
- e. Female partners of MSM
- f. People with a history of drug use (at least annually)
- g. Men and women from countries with a high HIV prevalence (>1%)
- h. Men and women who had sex with a person from countries with a high HIV prevalence (>1%)
- i. Sex workers (at least annually)
- j. Inmates
- k. Nomadic populations
- l. Homeless (at least annually)

By recommending an opt-out strategy the Portuguese authorities planned the introduction of HIV testing into routine clinical practice, increasing the number of people knowing their HIV status, ensuring earlier diagnoses and linkage to treatment, preventing further spread of the disease, and reducing the number of new-borns infected with HIV. In addition the reduction of stigma and discrimination associated with taking an HIV test would be reduced (DGS, 2014).

Window Period

Following the 2014 update of the HIV laboratory guidelines the window period is four weeks, if a 4th generation test has been used and the person tested has not been exposed to HIV within this period. In certain cases a repetition of a first negative test has been recommended as early as four weeks following the possible exposure (e.g. occupational or non-occupational exposure) or risk taking event (e.g. if the partner is HIV positive, for sex workers, IDUs, MSM, after sexual abuse / rape). For rapid tests the window period is 12 weeks with no further HIV transmission risk taken during this period (DGS, 2014)

Costs

Individuals wanting to know their HIV status can be tested free of charge in formal healthcare structures within the national health system or at other HIV testing settings throughout Portugal. The National Health Service or the NGOs carrying out the tests cover the costs. Costs for rapid HIV tests range from € 1 (specific test brand, not used at the moment) to € 14 (public price for Alere 4th Generation). At the National Health Service, costs range from € 1,40 (3rd generation rapid test) to € 5,63 (Alere 4th generation). A laboratory test for HIV is € 18,44 (HIV-1 and HIV-2 Ab) and € 99 for an ELISA confirmation per HIV type (Personal communication).

The percentage of reactive tests in different testing sites in Portugal is shown in table 9. The number needed to test to detect one new case varies between settings and data from the regional health administration, where the majority of tests are carried out is limited.

The overall cost of a testing procedure for one patient differs considerably from service to service. An analysis has been made of CheckpointLX's costs from the community perspective. The cost of voluntary counselling and testing services for one patient conducted in a community-based setting in Lisbon is around €75 (vs. € 40 in Athens and € 100 in Paris). The cost per reactive test is about € 2200 in Lisbon (vs. € 2000 in Athens and € 6200 in Paris). The authors of the study conclude that community-based services detect a high number of HIV cases at a relatively low cost in many European countries and therefore should be recommended for early detection of HIV and fast linkage to care (Perelman et al., 2017).

Table 9: Number of HIV tests performed in 2016 and percentage of reactive tests in different testing sites in Portugal

Testing site	Number of HIV tests in 2016	Reactive tests
Regional Health Administration	439.736	N/A
Health centres	3980	0.8 %
CAD testing centres	10.166	1.6 %
Community-based centres*	13669	1.93%
Community-based Screening Network* (Rede de Rastreio)	12261	1.7%

* There is a large overlap between the data from community-based sites, as the majority of centres are network members.

Source: Directorate General of Health - National Programme for HIV/AIDS, 2017, (DGS, 2017b)

Treatment, PEP and PrEP

Key objectives of the National Programme for HIV / AIDS and Tuberculosis Guidelines 2017 – 2020 are to ensure universality and equity in access to the best available treatment, to identify barriers and incentives to access as well as to promote the retention in care and the compliance to ART. In addition the promotion of and access to male and female condoms, Post-Exposure (PEP), Pre-Exposure Prophylaxis (PrEP) and aseptic material for injecting drug use are emphasized (DGS, 2017b).

All HIV positive individuals living in Portugal are eligible to have free access to ART, prescribed by specialist physicians in hospitals and provided by the National Health Service. Prescription and dispensation of drugs for ART, including PEP, must be registered in the national surveillance computer system (SI.VIDA), provided by the Directorate General of Health (POR, 2012).

The Ministry of Health has been discussing cost coverage and possible fee exemptions to provide PrEP for those eligible and to devise arrangements for monitoring and evaluating of a PrEP programme (AIDS MAP, 2017). The Directorate General of Health published the standard 025/2017 regarding PrEP in adults, addressing people with increased risk of acquiring an HIV infection in November 2017 (DGS, 2017a).

Policy Evaluations

There is neither any formal evaluation procedure nor an external evaluation process in Portugal. The Directorate General of Health has been monitoring the Portuguese HIV policies using indicators defined in the National Programme to Prevent and Control HIV / AIDS and Tuberculosis Guidelines 2012 – 2016 (POR, 2011) and annual reports have been published on these and various other HIV-related aspects (DGS, 2017b).

Good Practice Examples

The introduction of rapid tests for use by non-governmental organizations in 2010 has led to an increase in low-threshold testing opportunities for HIV / AIDS, viral hepatitis and other STIs. Community-based counselling and testing has now become an essential part of the Portuguese response and encouraging results have been observed. The establishment of a community-based screening network under the leadership of GAT (Rede de Rastreio) and in cooperation with public authorities and universities has successfully been complementing the services provided by the formal health system ensuring earlier diagnosis and appropriate linkage to care. In addition the network has been collecting and reporting data for epidemiologic surveillance of hard-to-reach populations, which are of high importance for policy development and distribution of resources (RDR, 2017).

CheckpointLX, a walk-in community-based HTS centre for the MSM community in Lisbon was established by Grupo Português de Ativistas sobre Tratamentos de VIH/SIDA (GAT) in 2011. A wide range of services related to HIV prevention, testing, counselling, treatment and care have been offered

free of charge and surveys have shown a high level of customer satisfaction. Outreach testing has been focusing on men who have sex with men through permanent marketing campaigns at community venues through, for example, flyers, posters, spots on local TV and mobile phone applications. CheckpointLX has been working closely with public authorities and researchers, collecting testing and surveillance data and carrying out biannually cohort surveys. Between 2011 and February 2015, 8311 HIV rapid tests were carried out with approximately 4% reactive tests in the MSM population. Between 2012 and 2015 4974 syphilis rapid tests and 552 hepatitis C rapid tests were also performed, with 5.4% and 1.1% reactive results, respectively (WHO, 2015b).

In 2012 GAT started the IN-Mouraria project, including harm reduction interventions and anonymous and free testing for HIV and other STIs, focusing on people who inject drugs and migrant populations. IN-Mouraria has been taking part in a broader network of organizations established and led by the local government to promote the rehabilitation of the Lisbon area. The project has been using peer-based outreach activities and the involvement of affiliated drug user and migrant associations to promote the referral to IN-Mouraria services. From October 2012 to December 2014 845 rapid HIV tests were carried out with an overall HIV seropositivity rate of 2.1% (4.4% in IDUs, 3.8% in MSM, 1.6% in migrants). Clients were then referred to infectious disease clinics and additional counselling services and support were offered. The project has been especially successful in reaching migrant populations, primarily from countries in sub-Saharan Africa and has been working in close partnership with migrant associations and other stakeholders throughout the local community (WHO, 2015b).

Challenges

Portugal has faced increasing challenges in ensuring HIV prevention and access to treatment during years of economic austerity. HIV response in recent years has suffered greatly from budget cuts in social welfare and social interventions, restructuring of public structures, reduction in pharmaceutical spending and decreasing civil society interventions in the field of HIV prevention, testing, and health literacy (EATG, 2014).

Civil society representatives have stressed the need to improve access to HIV prevention, diagnosis and treatment for migrant populations, in which a rising HIV prevalence has been observed. They have called for a holistic approach in the provision of services, including screening for hepatitis, tuberculosis and other sexually transmitted infections. Furthermore all forms of discrimination need to be eliminated in order to increase access to HIV services and to end the AIDS epidemic as a public health threat by 2030 (UNAIDS, 2017c).

A study on the knowledge about HIV and HIV testing in primary care has been carried out as part of the European OptTEST project. Answers received from healthcare professionals showed knowledge gaps regarding the prevention, transmission and risk factors for an HIV infection. Only 45% of the health professionals were aware of the Directorate General of Health's guidelines for HIV testing. The use of rapid tests for HIV appeared to be limited in many primary care settings. Therefore the recommendation has been made to implement a comprehensive training package for healthcare professionals, including functional and practical information on testing, counselling strategies and procedures. In addition investments in indicator condition guided testing and initiatives to reduce discrimination and stigma towards PLHIV and key affected groups are to be encouraged (Simões, 2017).

1.5 SWEDEN



Sweden is the first country to achieve the UNAIDS/WHO 90-90-90 targets. Researchers estimated that by the end of 2015 only about 10% of all HIV-infected individuals in Sweden remained undiagnosed. This estimate was based on data from the Swedish InfCare HIV Cohort study, which includes almost 100% of individuals diagnosed with HIV, together with HIV surveillance data reported by the Public Health Agency of Sweden, 99.8% of diagnosed patients were linked to care and 95.1% were on ART. 94.7% of those receiving ART were in suppression with a viral load < 50 HIV-1 RNA copies/ml (Gisslén et al., 2017).

Table 10: HIV situation in Sweden

HIV STATISTICS	Sweden
General population (in Million) ¹	9.8
Persons living with HIV (2016)	7718
% of PLHIV in the general population	0,08%
90 – 90 – 90 TARGETS ²	2015
1 st 90: % of PLHIV knowing their status	90%
2 nd 90: % of PLHIV diagnosed and on ART	95%
3 rd 90: % of PLHIV, ART with viral suppression	95%
NEW DIAGNOSIS in 2016 ³	430
New HIV diagnoses per 100.000 population	4.3
• Male	5.7
• Female	3.5
By mode of transmission ³	
• MSM	31.4%
• Heterosexual contact	46.5%
• Injecting drug use (IDU)	6.1%
• Other or undetermined	15.1%

Sources:

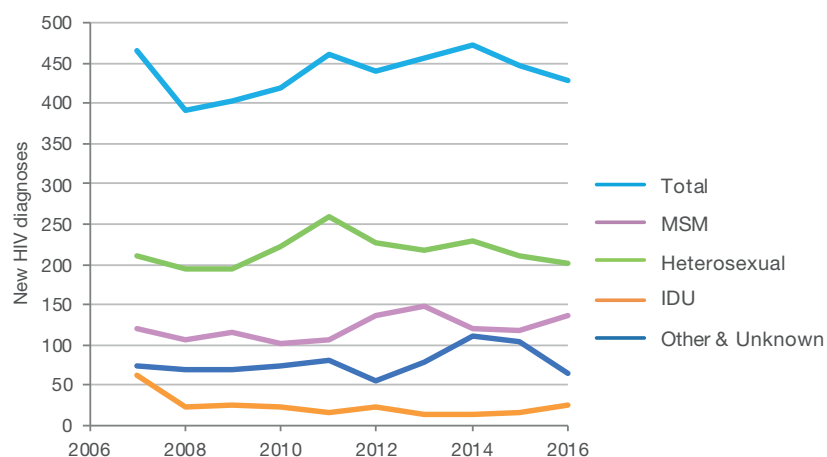
1 World Population Prospects, 2015 Revision, (UNDESA, 2015)

2 Continuum of HIV care, (ECDC, 2017)

3 Informationsinsats HIV, Folkhälsomyndigheten, 2017 (Folkhälsomyndigheten, 2017b)

Since the 1990s the largest numbers of new HIV infections were diagnosed in heterosexual migrants infected prior to their arrival in Sweden. The majority of new domestic HIV infections were diagnosed in the MSM community (SWE-GOV, 2012). For the past 10 years the number of newly diagnosed HIV infections has been relatively stable in Sweden. In 2016 a total number of 450 new HIV diagnoses were reported (Figure 12). Almost 80% of all people reported with an HIV-infection in 2016 were foreign-born with many of these infections occurring in Thailand, Eritrea and Spain (Folkhälsomyndigheten, 2017b).

Figure 12: New HIV diagnoses, total and by mode of transmission, Sweden 2007-2016



Source: HIV/AIDS Surveillance in Europe 2017 – 2016 data, (ECDC, 2017e);

About 100.000 HIV tests are performed annually in Sweden in addition to the testing of blood donors or in pregnant screening programs. Studies show that about 66%, especially heterosexuals and IDUs, were diagnosed late, more than six months after becoming infected, regardless of their country of birth (Folkhälsomyndigheten, 2013).

A national registry, InfCareHIV, has included all patients being treated for HIV in Sweden and all of the 30 Swedish HIV clinics / units have participated. The main purpose of the registry is to provide equitable access to and improve health care services for all HIV-infected persons as well as to identify individuals and groups with poorer treatment outcomes requiring more attention and resources. Through online consultations using a nationwide software, smaller clinics can receive advice and local support from Karolinska Institutet, the main academic health center in Sweden (INFCARE, 2016).

National HIV strategy

The **National Strategy to Combat HIV/AIDS and Certain Other Communicable Diseases 2006-2016** was developed by the Swedish Institute for Communicable Diseases Control and adopted by the Swedish parliament in 2006. It has been using an integrated response from all relevant sectors, including health, education, social welfare, prison and probation as well as migration services. The strategy emphasizes the need for close cooperation and coordination between sectors, government bodies and non-governmental organisations. All major stakeholders were therefore invited to participate in the needs assessment and strategy development process (SWE-GOV, 2006).

The aim of the strategy is to limit the spread of HIV and other STIs, reducing consequences of the infections for the individual and society.

The main objectives are:

- To reduce the incidence of HIV infections within Sweden by half
- To offer HIV testing and counselling to asylum seekers and their relatives as well as to others who have returned from countries with a generalized HIV epidemic
- To increase the knowledge about HIV and its consequences in the public sector, occupational sector and the general population

An update of the national HIV strategy has been planned with a particular focus on the measurable goals. The Public Health Agency of Sweden's review is currently (November 2017) on referral to other governmental agencies, county councils and NGOs.

National HIV Prevention Activities

Sweden's HIV prevention work has been based on a rights-based approach with an emphasis on sexual rights, ensuring that everyone, regardless of gender, ethnic background, age, sexual orientation or disability, has the right to appropriate information about their own body and sexuality and access to services. (SWE-GOV, 2012)

A wide range of HIV and STI prevention efforts and activities have been carried out throughout Sweden, particularly at regional and local level through the county councils and NGOs supported with funding from the national government and coordinated by the Public Health Agency of Sweden (Folkhälsomyndigheten, 2014). The Public Health Agency of Sweden (Folkhälsomyndigheten), which was formed in 2014 through a merger of the Swedish Institute for Communicable Diseases Control, the Swedish National Institute of Public Health and some parts of the National Board of Health and Welfare, is responsible for monitoring the national HIV and STI strategy and for prevention and surveillance activities in this field. The agency has been using a number of web portals for its information campaigns, e.g. to address the MSM community (www.sentry.nu) and innovative approaches like motivational interviewing (Folkhälsomyndigheten, 2017a).

The Swedish Federation for Lesbian, Gay, Bisexual, Transgender and Queer Rights (RFSL) has been involved in HIV and STI prevention both at an individual and societal level as well as in advocacy work since 1982. The work has contributed to an improved knowledge about HIV and STIs especially in target groups (RFSL, 2017a).

National HIV Strategy / Policy for HIV Testing

Sweden does not have a specific national HIV testing strategy. The majority of Swedish counties have implemented regional HIV/STI programmes, based on the national guidance documents published by the Public Health Agency of Sweden in cooperation with the Reference Group for Antiviral Therapy (RAV) in 2015 (Folkhälsomyndigheten, 2015c).

The national HIV strategy identified seven key population groups at higher risk of HIV exposure: MSM, injecting drug users, immigrants, youth, people travelling abroad, people buying and selling sex as well as pregnant women. Prevention and testing activities have been especially directed at MSM, IDU and migrants, with information, counselling and testing services adapted to the needs of the specific groups (SWE-GOV, 2006).

As the Swedish education, health and social care systems are decentralised, the responsibility for HIV and STI prevention and testing programmes aimed at the general population as well as key population groups lies with the county councils (health care) and the municipalities (schools and social services). These programmes have been funded by the national government and regulated by various laws, such as the Communicable Disease Prevention Act and the Health and Medical Services Act (SWE-GOV, 2012).

Voluntary Counselling and Testing for HIV and other STIs is available for free throughout Sweden. Following a positive test result contact tracing and partner notification is mandatory for all clinicians who diagnose HIV (SWE-GOV, 2012).

Coordination of HIV Testing

The Ministry of Health and Social Affairs is responsible for health and medical care, public health and social services policy and is also in charge of the overall responsibility for HIV policy and prevention. The Public Health Agency of Sweden is in charge of communication strategies and campaigns in the area of HIV and STIs, including information and education about HIV prevention and testing opportunities. County councils, municipalities and NGOs organize HIV and STI prevention and testing programmes. NGOs play an important role in reaching target population and some offer anonymous testing opportunities as well (SWE-GOV, 2012).

HIV Sweden, for example, is a national umbrella organization of regional and national patient associations working to improve the life of people with HIV and their families. The organization provides a detailed list of most of the HIV testing centres in Sweden on its website (HIV-SVE, 2017).

Access

Free testing is available to all throughout Sweden. It is anonymous as long as the HIV test result is negative.

Sweden has a wide range of service-providers offering HIV and STI testing. These include:

- Primary health care centres in the municipalities
- STI clinics, infectious disease clinics and gynaecological clinics in public hospitals
- NGOs with or without clinical supervision
- Target population centres (financed by county councils or state grants) are being used for
 - MSM (e.g. at Checkpoints)
 - Asylum seekers
 - IDUs (repeated HIV testing is mandatory for participants in needle-exchange programmes)

All blood donors are screened for HIV both before their first donation and every time they donate blood or plasma. HIV testing is offered to all pregnant women and performed as an opt-out routine. HIV testing should also be offered to people within six months following their return from a country with a generalized HIV epidemic.

According to the “Health and Medical Care for Asylum Seekers and Others Act” county councils should offer a health examination to all migrants within two months of arriving in Sweden. In addition to a health interview, laboratory tests including voluntary screening for HIV and other examinations have been recommended. The proportion of migrants and asylum seekers taking this health examination has varied considerably between counties (SWE-GOV, 2012).

HIV self-testing and self-sampling are not permitted in Sweden. While test-kits are available on the Internet, imported from other European countries, their use is not recommended by the Public Health Agency of Sweden (Folkhälsomyndigheten, 2015b). There are home tests for other diseases in Sweden, e.g. Chlamydia, that are sold through the pharmacies (RFSL, 2015).

Counselling

All testing centres for HIV and other sexually transmitted diseases run by county councils and some NGOs provide pre- and post-test counselling services free of charge. The county councils supported by the national government cover the costs for these services.

Partner Notification

Under the Swedish “Communicable Diseases Act” infections with HIV, syphilis, chlamydia, gonorrhoea, hepatitis B and C are notifiable. It is therefore compulsory for healthcare providers to initiate partner notification, for index patients to accept partner notification and for partners to undergo testing and, if indicated, treatment. Partner notification services vary between counties. In some counties patients are referred to STI centres with specialist contact tracing staff (non-HIV infections) or to infectious diseases clinics at university hospitals (HIV infections). In other counties healthcare providers making an HIV or STI diagnosis also initiate partner notification together with the patient. This is the most common approach in Sweden. However in some cases, when index patients or their partner(s) do not follow the partner notification instructions, they can be referred to the county medical officers, who can contact the individual by letter, phone or, if necessary, a home visit (ECDC, 2013).

Process

The main HIV tests used in Sweden are:

- **4th generation ELISA** (anti-HIV-1 & anti-HIV-2 antibodies, p24 antigen) followed by an Immunoblot or Western blot to confirm positive results
- **Combined rapid point-of-care tests** (HIV-1- & HIV-2-antibodies plus p24 antigen) followed by 4th generation ELISA and an Immunoblot to confirm positive results

National HIV Testing Guidelines

There are no national HIV testing guidelines, but guidance on the “Follow-up after exposition to HIV” published by the Public Health Agency of Sweden and the Reference Group for Antiviral Therapy has been used (Folkhälsomyndigheten, 2015c). County councils align this to their own routine according to their respective local organisation.

In Sweden counselling and testing for HIV is voluntary and in general an opt-in approach is being used. However according to the Swedish Communicable Diseases Act, any person who believes or suspects that they might have an infectious disease is obliged to take measures to protect others. In addition the person is advised to see a physician and to get tested, if required. In case of a positive test for one of the notifiable diseases (HIV, syphilis, chlamydia, gonorrhoea, hepatitis B and C) partner notification must be initiated and testing of those partners is mandatory (Folkhälsomyndigheten, 2015c).

Window Period

A comprehensive review and analysis by the Public Health Agency of Sweden and the Reference Group for Antiviral Therapy has led to new recommendations for follow-up times after exposure to HIV (Gaines et al., 2016):

- When a laboratory-based combination 4th generation test is used, a 6-week window period after a suspected HIV exposure or after termination of PEP / PrEP prophylaxis is recommended.
- When a rapid response test is used an 8-week window period after a suspected HIV exposure or after termination of PEP / PrEP prophylaxis is recommended.
- If a HIV-2 exposition is suspected, a 12-week window period is recommended for both 4th generation laboratory tests and rapid response tests.

(Folkhälsomyndigheten, 2015c)

Costs

HIV testing is available and free of charge to anyone throughout Sweden. The state and the counties cover the costs for testing and treatment of HIV and other communicable diseases.

Treatment, PEP and PrEP

HIV treatment and care is integrated in the Swedish health care system, providing services and medication free of charge for the patient. This also applies to all asylum seekers and undocumented migrants in Sweden, who are given access to subsidised health care on the same terms as Swedish citizens. All individuals tested positive for HIV are connected to an infectious disease clinic and start ART independent of their CD4 cell count.

The Swedish Reference Group for Antiviral Therapy (RAV) has published a review and position statement on the minimal risk of HIV transmission from patients on ART. This report received a lot of media attention and is also considered to have been influential in respect to the jurisprudence in criminal court cases in Sweden regarding HIV exposure through sexual contact (Folkhälsomyndigheten, 2014).

PrEP is approved by the Swedish Medical Products Agency and can be administered by doctors to individuals with a greatly increased risk of an HIV infection. The Swedish Reference Group for Antiviral Therapy published guidelines on how PrEP should be prescribed (RAV, 2017). Due to the high costs and as the cost coverage has not been finally decided on, the accessibility of PrEP remains low (RFSL, 2017b).

Policy Evaluations

The national HIV strategy has been reviewed by the Public Health Agency of Sweden and with the support of other relevant actors (like County Councils or NGOs) an update is currently being developed.

Good Practice Examples

Sweden has reached the goal of 90-90-90 set by WHO and UNAIDS by using an integrated response from all relevant sectors, including health, education, social welfare, prison and probation as well as migration services. Close cooperation and coordination between sectors, government bodies and non-governmental organisations has proven to be valuable for the development and implementation of the HIV strategy and related policies and approaches, including prevention and testing. A national, multisectoral conference on HIV and STI prevention in October 2013 was organised by the Public Health Agency of Sweden leading to increased cooperation and attracting a great amount of attention in the media (Folkhälsomyndigheten, 2014).

Challenges

A 2015 survey including about 2500 people revealed that there were knowledge gaps and negative attitudes related to HIV in the general, adult population. Almost 60% were not aware of the effectiveness of ART, reducing the infectiveness of patients significantly and 30% of the participants did not know that they could have an HIV test in their primary healthcare center. 20% answered that they would probably avoid close contact with an HIV-infected person (Folkhälsomyndigheten, 2015a).

Increasing testing in key populations and consequently being able to improve earlier diagnosis has also remained as a challenge in Sweden. More than 60% of all HIV patients diagnosed in 2011 were late presenters (CD4 <350 at time of diagnosis). While the majority of these patients were heterosexual immigrants, late presenters existed in all of the key populations (Widgren et al., 2014). This also stresses the importance of developing and implementing innovative methods to reach migrants and other key populations using appropriate information and to offer counselling and testing (Folkhälsomyndigheten, 2014).

Therefore the Public Health Agency of Sweden and the local authorities have been aiming at increasing knowledge about HIV and other STIs in the general population, key population groups and within the healthcare sector. County Medical Officers have been encouraged to update healthcare professionals, increasing their competence for testing, counselling and tracking HIV and other STIs. Many primary healthcare clinics have been given support in developing routines for anonymous HIV and STI testing as well as for partner notification services.

1.6 SWITZERLAND



The HIV situation in Switzerland can be described as a concentrated epidemic with about 500 to 600 new HIV infections per year since 2009 (Figure 13) and about 0.2% of the population living with HIV. In 2015 about 18% of persons living with HIV in Switzerland were estimated to be not aware of their serostatus. More than 91% of those diagnosed with HIV were on ART (Table 11).

Table 11: HIV situation in Switzerland

HIV STATISTICS	Switzerland
General population (in Million) ¹	8.3
Persons living with HIV (2015) ²	15.200
% of PLHIV in the general population	0.2%
90 – 90 – 90 TARGETS ³	2012
1 st 90: % of PLHIV knowing their status	82%
2 nd 90: % of PLHIV diagnosed and on ART	91%
3 rd 90: % of PLHIV, ART with viral suppression	97%
NEW DIAGNOSES ⁴	2016
New HIV diagnoses	542
New HIV diagnoses per 100.000 population	6.4
• Male	10.1
• Female	2.7
By mode of transmission	
• MSM	45.2%
• Heterosexual contact	40.9%
• Injecting drug use (IDU)	2.4%
• Other or undetermined	11.5%

Sources:

1 World Population Prospects, 2015 Revision, (UNDESA, 2015)

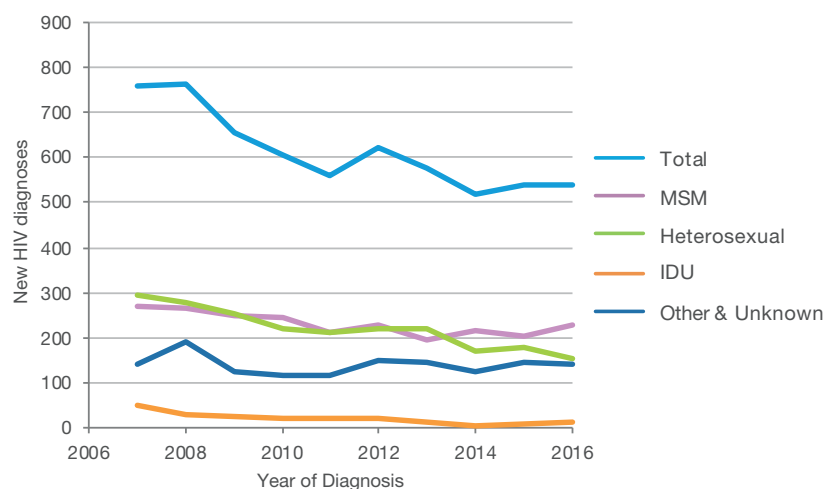
2 The HIV care cascade in Switzerland, (Kohler et al., 2015)

3 Continuum of HIV care, (ECDC, 2017)

4 Jahresbericht zur HIV- und STI-Epidemiologie in der Schweiz (BAG, 2017d)

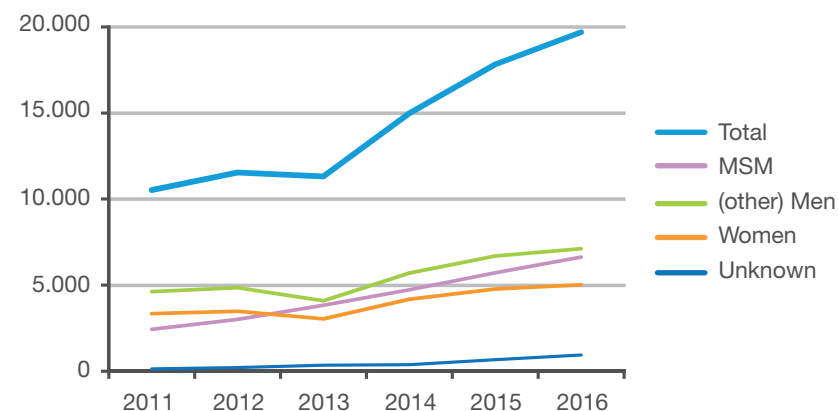
The main modes of HIV transmission in Switzerland are through sex between men (49.3%) and heterosexual contacts (34.4%), transmission through injecting drug use is relatively low (0.02%), and in about 16.3% of newly diagnosed cases the mode of transmission remains unclear. While the percentage of new infections among men who have sex with men has been decreasing over time, this group remains one of the high-risk groups in Switzerland together with migrants from high-prevalence countries, especially from Sub-Saharan Africa, and injecting drug users (BAG, 2016a).

Figure 13: New HIV diagnoses, total and by mode of transmission, Switzerland 2007-2016



Source: Source: HIV/AIDS Surveillance in Europe 2017 – 2016 data (ECDC, 2017e)

Figure 14: HIV-Tests performed in VCT-Centres in Switzerland, 2011-2016



Source: BAG Bulletin 43/17 (BAG, 2017d)

Until recently data on the number of performed HIV tests has not been collected from laboratories in Switzerland systematically. However many of the voluntary counselling and testing centres have been using a web-tool, BerDa (Beratungsleitfaden und Datenverwaltungssystem für VCT-Stellen), to facilitate a high standard of counselling at first, but also to collect anonymous statistical data from their clients to identify various trends in Switzerland (BAG, 2011b). This data has shown a steep increase in the number of HIV tests performed, especially between 2013 and 2016, which is not only due to the increasing number of testing centres now reporting to the BerDa system, but especially due to a higher motivation for testing in MSM communities (Figure 14). Since January 2016 the new Swiss Epidemics Act has been implemented, including the mandatory reporting of the number of HIV tests conducted. First results and an analysis are expected for 2018 (BAG, 2017d).

Knowledge about HIV testing opportunities in Switzerland appears to be widespread. The 2017 synthesis report by the University of Lausanne presented a survey showing that the majority of participants were aware of local HIV testing facilities (MSM 90%; sex workers 77%, migrants from sub-Saharan Africa 73%). Overall testing rates in high-risk populations within a 12-month period prior to the survey also seemed to be much higher than in the general population (e.g. sex workers 66%; MSM 40%; general population 5%) (Lociciro et al., 2017).

Since 1988 a large proportion of all diagnosed HIV-infected individuals in Switzerland have been registered in the Swiss HIV Cohort Study (SHCS). The SHCS is a simple, collaborative partnership between the infectious disease outpatient units of all Swiss university hospitals, two cantonal hospitals and a few smaller hospitals as well as private physicians treating HIV patients. The main goals of the cohort study have been to provide optimal patient care, to reduce HIV transmission and to conduct research on HIV treatment, pathogenesis, co-infections, immunology and virus – host interactions (SHCS, 2017).

National HIV strategy

The **Swiss National Programme for HIV and other Sexually Transmitted Infections (NPHS) 2011-2017** was originally developed in a participatory process with key stakeholders and has now been extended for four more years. It has been based on the Swiss Epidemics Act and covers all issues concerning prevention, diagnosis and treatment of HIV and other STIs, including chlamydia, syphilis, gonorrhoea, hepatitis, human papilloma virus, lymphogranuloma venereum and herpes (BAG, 2011c).

This comprehensive strategy has been developed in response to four main challenges:

- HIV is recognized as a severe, complex and chronic disease, for which a vaccination, cure or eradication are not yet in sight.
- Life-long treatment for one infected patient is estimated to cost up to 1 million Swiss francs (or 25.000 CHF / year).
- Untreated STIs can have severe consequences, like chronic diseases, infertility, cancer and pregnancy complications.
- HIV and STIs continue to have an epidemic potential and are therefore considered to be a potential threat to public health in Switzerland.

The main goals of the Swiss strategy are:

1. To empower the Swiss population through suitable means of sensitisation and education and to protect their rights in the realm of sexuality.
2. To identify effective and innovative measures of behavioural and contextual prevention reducing the transmission risk of HIV and other STI.
3. To diagnose infected individuals early, offer comprehensive services and start ART soon after the diagnosis to improve the life of the individual and to reduce the risk of transmission.
4. To ensure that HIV and STI work is based on scientific evidence, is aligned with the needs of and developed in cooperation with the target groups to achieve a lasting effect.

(BAG, 2011c)

National HIV Prevention Activities

The prevention and early detection of HIV infections have been core elements of the Swiss NPHS 2011-2017. Prevention policies and activities are based on the Epidemics Act, addressing the general population, sexually active individuals with a heightened exposure risk for HIV and/or STIs and individuals with HIV and/or an STI as well as their (non-infected) partners. HIV prevention activities in Switzerland have been based on the “learning” principle (how to protect oneself and to protect others) using a non-discriminatory approach (BAG, 2011a).

To maintain the prevalence of HIV at a low level in the general population and to prevent the further spread of the infection among all sexually active people living in Switzerland, national programmes and campaigns are being used to inform about risks, protective measures (e.g. good quality condoms), rights and the availability of counselling services and contraceptives. The Federal government has been supporting sexuality education nationwide, e.g. in schools and NGOs, raising awareness among sex workers and their clients as well as among people travelling abroad. Qualified counselling on sexual health has been provided through the national LOVE LIFE campaign and an Internet platform has been used to reach the general population (BAG, 2017e).

Target group specific counselling and voluntary screening programmes are being used to slow the spread of HIV and/or STIs within high-risk groups (e.g. MSM, Migrants from high-prevalence countries, sex workers, transgender people, prisoners) and to contain the concentrated epidemic. These preventive measures focus both on better individual protection

(behavioural prevention) and on the socio-economic and legal conditions that sustain and promote preventive behaviour (structural prevention).

Since 2012 the national prevention strategy for MSM, known as the Urgent Action Plan, has been developed and implemented in collaboration with the Swiss AIDS Federation and the Checkpoint sexual health centres, including the Break the Chains, STOP SYPHILIS, and #undetected annual campaigns, which will be continued from 2017 onwards under the new names STARMAN and SECURION (BAG, 2017c; AHS, 2017).

The FOPH has been working with the Swiss AIDS Federation, Swiss Sexual Health and other partners to prevent HIV and/or STIs in migrant and other vulnerable populations (e.g. sex workers), by developing a national “Migration and vulnerability factors framework” (MV Framework). This based on three fields of action (BAG, 2017f):

- Human rights, participation, access to healthcare, empowerment of those concerned
- Access to information, to means of prevention, contraception and vaccination
- Screening, diagnosis, treatment and voluntary disclosure to partners

One example for this framework approach is the “Get Tested” campaign, aimed to create an interactive, community-oriented tool for prevention work in African communities in Switzerland, which has been run by the Swiss AIDS Federation since November 2017 (AIDS-Hilfe, 2017).

To prevent the risk of further transmission individuals with HIV and/or an STI are being informed about the respective infection and its consequences and are encouraged to share this information with their partners, counselling services are being offered. In addition efforts are being undertaken to reduce discrimination against and stigmatisation of HIV-positive individuals and to encourage the use of voluntary counselling and testing services as well as other treatment and care opportunities (BAG, 2017g).

National HIV Testing Strategy / Policy

The Swiss HIV testing policy was included in the NPHS 2011-2017, which was constructed on three axis of intervention, each addressing particular population groups:

1. The general population
2. Sexually active individuals with a heightened exposure risk for HIV and/or STIs (MSM, Migrants from high-prevalence countries, IDUs, prisoners)
3. Individuals with HIV and/or an STI as well as their (non-infected) partners

The Swiss HIV testing policy has been promoting a voluntary counselling and testing approach, focusing on people with a high risk of an infection and on people in close contact with groups with an increased HIV-prevalence. Tests have either been performed at the request of the individual on the basis of the principle of voluntary counselling and testing or offered by a physician or other service provider (Provider induced counselling and testing, PICT). An HIV test is obligatory when donating blood and offered systematically in specific, defined medical cases, e.g. during pregnancy, requiring the informed consent of the individual concerned and using an opt-in approach.

A range of providers (e.g. hospitals, Checkpoints etc.) offers voluntary counselling and testing services for HIV and other STIs. These providers are required to follow the Swiss national VCT guidelines to guarantee the highest possible standard. These include systematic documentation of a risk analysis and counselling prior to and following tests. The Federal Office of Public Health has developed a web tool, BerDa, to ensure a high level

of counselling quality in VCT centres. This is based on a self-administered questionnaire, creating a risk profile for the person requesting the test. BerDa offers a structure for the consultation and a series of targeted recommendations relevant to the answers provided and to the client's sexual behaviour. The tool also collects anonymous statistical data from VCT centre clients, helping to identify various trends in Switzerland (BAG, 2011b).

In addition to the VCT approach, Switzerland has been promoting the PICT approach, where physicians usually suggest an HIV test to the patient, if certain indicators e.g. clinical symptoms such as frequent fevers and viral illnesses have been observed, STIs or tuberculosis have been diagnosed or risky behaviour has been reported. PICT requires the informed consent of the patient and counselling should be given prior and following the test, even if the test result is negative, depending on the individual's susceptibility to counselling. Special PICT guidelines have been developed by the Swiss Federal Commission for Sexual Health (FCSH) and published by the Federal Office of Public Health (BAG, 2015).

Coordination of HIV Testing

The Federal Office of Public Health (FOPH) coordinates the national response to HIV and AIDS strongly encouraging the voluntary counselling and testing (VCT) approach for HIV and other STIs as well as the provider-initiated approach (PICT). It is supported by the Federal Commission for Sexual Health, an extra-parliamentary commission providing strategic and political advice in the fight against HIV / AIDS and other STIs. In addition the FOPH has been working closely with Aids-Hilfe Schweiz, a national association of NGOs working in the field of HIV/AIDS, which is co-organizing national awareness campaigns and working at the local level offering e.g. information and education opportunities for people living with HIV, their partners and relatives as well as other interested members of the public. Sexual Health Switzerland, an independent foundation aiming at promoting sexual and reproductive health in Switzerland, is also very active in this area. This foundation has also been involved in policy-making activities at the national and cantonal levels. Cantonal authorities are responsible for HIV and STI testing services offered by a range of providers (BAG, 2016c)

Access

A broad range of actors provides HIV and STI testing services (BAG, 2017a):

- Specialist clinic staff (doctors or nurses; anonymous testing possible)
- Any doctor or nurse (not necessarily in specialist clinics)
- VCT-centres offering anonymous testing (often run by NGOs)
- NGOs with clinical supervision (not using the VCT guidelines)
- Gay Health Centres (five “Checkpoints”)

A special web tool (“Risiko-Check”), information on the location of suitable testing centers as well as additional information is available on the website of the LOVE Life national campaign (BAG, 2017e).

Checkpoints are health centres offering a broad range of medical, psychological and social services mainly for men who have sex with men. Checkpoint Zurich and Lausanne further offer dedicated counselling for transgender people. Persons wishing to be tested have to pay directly for HIV- and syphilis tests (Checkpoint, 2017). Some Checkpoints, e.g. in Zurich, also conduct outreach activities, offering mobile counselling and testing services in clubs, bars, saunas or other places where high-risk groups meet. These tests follow the national VCT guidelines and results will only be disclosed in the checkpoint on the next day permitting adequate counselling services (AHS/BAG, 2014).

In Switzerland the Federal Commission for Sexual Health does not recommend home sampling or self-testing (AHS/BAG, 2014; EKSG, 2013) but a policy allowing these approaches is currently being discussed.

Counselling

All testing centres in Switzerland are required to offer psychosocial support and additional counselling services. Costs for these services are either covered by the health insurance (for non-anonymous tests only, but restrictions apply) or by the organization offering the services, but in most cases individuals have to pay about 60 CHF for testing and counselling services by themselves. As part of the web tool BerDa, high quality counselling is envisaged through the provision of targeted recommendations relevant to the client’s individual profile and sexual behaviour. The tool is also being used to identify various trends in Switzerland by collecting anonymous statistical data from the VCT centers (BAG, 2017b).

Partner Notification

Switzerland does not have a legislative framework on partner notification and there are no specialized professionals who are specifically trained in this field, but advice on this issue is routinely offered during counselling services, which are based on the Swiss VCT- and PICT-guidelines (BAG, 2011b). The “normalisation of voluntary partner information” was an aspect included in the national HIV strategy (BAG, 2011c).

Process

The main HIV tests used in Switzerland are:

- **4th generation ELISA** (anti-HIV-1 & anti-HIV-2 antibodies, p24 antigen) followed by an Immunoblot to confirm positive results and - if a HIV-2-infection is suspected – a PCR.
- **Combined rapid point-of-care tests** (HIV-1- & HIV-2-antibodies plus p24 antigen) followed by 4th generation ELISA and an Immunoblot to confirm positive results

Further tests to determine the viral load and to identify possible resistances to antiretroviral drugs are routinely conducted by the National Centre for Retroviruses (NZR) or one of the 11 regional notification laboratories.

National HIV Testing Guidelines

Since 1985 the Swiss Federal Office of Public Health has generated specific HIV testing guidelines to ensure the highest possible diagnostic standards and to identify the most suitable antiretroviral therapy for individual patients. The guidelines have been revised periodically, the most recent revision was published in 2013 (BAG, 2013).

These guidelines are based on four main questions:

1. Is the patient really infected with HIV?
2. How can the identified virus be characterized (e.g. HIV 1 or 2, group, drug resistances present?)
3. How high is the viral load?
4. What is the percentage of patients with recent HIV-infections (< 12 months) among all patients with a positive test result?

Accredited laboratories, medical practices and special HIV testing centres offer HIV screening tests. The National Centre for Retroviruses (NZR), together with 11 regional notification laboratories, is responsible for conducting the HIV confirmation tests using a standardized approach (BAG, 2013). Following a positive screening test a new blood sample (EDTA) has to be sent to confirm the infection to either the National Centre for Retroviruses (including all paediatric cases) or one of the regional notification laboratories. These are responsible for providing all the required information listed in the national HIV testing guidelines. In addition they are in charge of registering a large proportion of all HIV-infected individuals in Switzerland into the Swiss HIV Cohort Study (SHCS).

Window Period

FOPH has recommended the use of a combined rapid point-of-care test 10-14 days after a risk-taking event, if the patient does not have any clinical symptoms indicating a possible HIV infection, which would require an immediate test. If the first screening test is negative, a second combined test should be conducted two weeks after the initial one. If the second one is also negative, a third combined test should be taken three months after the risk-taking event to definitely exclude an HIV infection (BAG, 2013). The Federal Commission for Sexual Health is currently discussing reducing this 3-month window period following the example of most other European countries.

Costs

HIV-testing, or even more so STI-testing are expensive for clients in Switzerland. The high costs of testing are the main barrier for STI-testing in Switzerland. The costs for VCT for HIV in Switzerland are 60 CHF in most places. Only in very exceptional situations, costs are covered by the health insurance, and even if they are, because of obligatory deductibles and co-payments, the client typically pays the bill. At testing centres, a person wishing to be tested voluntarily often needs to pay privately (approximately CHF 60 per test) (GNP+, 2017b).

Using data collected through the BerDa system by all 20 Swiss VCT testing centers over a 5-year period, a cost-effectiveness analysis was conducted and the number needed to test (NNT) as well as the positive predictive value (PPV) were calculated (Table 12). From the four different VCT-site categories,

Checkpoints were the most cost-effective and showed the highest PPV (92%). Estimated costs per HIV diagnosis were CHF 3.600 at Checkpoints, while in other settings like clinics and testing centers run by the AIDS-Hilfen the costs were more than five times higher. Cost effectiveness was lowest in ProFa-based HIV-testing sites (CHF 203.250 per diagnosis).

Table 12: Number needed to test and positive predictive value of HIV tests in Swiss VCT-sites (2008-2012)

Test site category	Check-points	AIDS-Hilfen	Clinics	ProFa	Total
N tested	11 082	5 860	23 717	4 065	44 724
N false positive	14	14	60	1	89
N confirmed	155	18	60	1	234
% false positive	0.1%	0.2%	0.3%	0.02%	0.2%
% confirmed pos.	1.4%	0.3%	0.3%	0.02%	0.5%
NNT	71	326	395	4065	191
PPV	92%	56%	50%	50%	72%
CHF per diagnosis	3 600	16 300	19 800	203 250	9 600

Source: Schmidt et al., BAG, Deutsch-Österreichischer AIDS-Kongress 2013 (Schmidt, 2013)

Treatment, PEP and PrEP

HIV treatment in Switzerland is covered by the patient's health insurance, but most patients are required to pay deductibles (of about 300 to 2500 CHF per year) and co-payments for costs above the deductible. This means that all HIV patients in Switzerland pay at least about 1100 CHF for their treatment. Undocumented migrants might only have restricted access to HIV treatment. The Federal Commission for Sexual Health recommends starting post-exposure prophylaxis (PEP) as soon as possible, but not later than 48 hours after a risk-taking event. The decision for PEP and the choice of medication should be based on a comprehensive risk assessment. When medically indicated, costs for PEP are covered by the health insurance (BAG, 2014). If a person has a substantially increased risk of an HIV infection and has a confirmed negative HIV serology as well as a number of other pre-requisites (e.g. normal renal function), a physician can prescribe oral pre-exposure prophylaxis (PrEP) for HIV prevention on an off-label basis. The physician is therefore liable for any occurring adverse effects and drug costs are not covered by the health insurance (BAG, 2016b).

PrEP is not licensed in Switzerland. Medical prescriptions are therefore only possible off label. Clients can buy PrEP at the pharmacy on presenting a doctor's prescription for CHF 900 (Truvada®). Alternatively they can order the respective generics online and import them without prescription at 5-10% of that price.

Good Practice Examples

The Swiss HIV Cohort Study, including a high proportion of all diagnosed HIV-infected individuals since 1988, has proven to be a very valuable tool to help provide optimal patient care, reduce HIV transmission and conduct research on HIV treatment, pathogenesis, co-infections, immunology and virus – host interactions (SHCS, 2017).

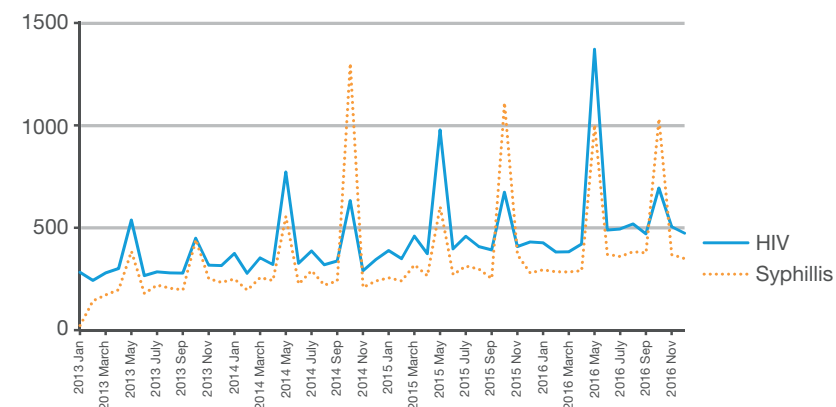
The voluntary counselling and testing approach, especially when conducted in Checkpoints, has shown very encouraging results with an increasing number of people using these easy-to-access and anonymous testing opportunities. In addition the BerDa webtool used by these VCT centers has also provided important information for policy planning. Cost-effectiveness studies support this approach (Checkpoint, 2017).

Another good practice example is the community action campaign Break the Chains (BTC), which was designed by the FOPH and the Swiss Aids Federation and has been implemented each spring since 2012. The campaign is part of the NPHS 2011 - 2017 and has aimed at interrupting the HIV transmission chains among MSM and at reducing the “community viral load” using a community action approach. Individuals have been encouraged to avoid any risk of HIV transmission during a one-month period (in April) and then to get tested for HIV in May (Frey et al., 2014).

The BTC campaign has been closely linked to the STOP SYPHILIS campaign, in which guidance and free testing for syphilis and other STIs has been offered during the month of October (AIDS-Hilfe, 2013). An analysis has shown the

success of both campaigns, which are effectively complementing each other (Figure 15).

Figure 15: Number of HIV and Syphilis tests conducted in VCT centres per month, 2013 - 2016



Source: Swiss Federal Office of Public Health, Bulletin 43/17, (BAG, 2017d)

Challenges

Despite many prevention efforts and testing campaigns the HIV incidence in Switzerland has been relatively stable at a low level since the late 1990s. A number of factors have contributed to this, e.g. changing risk-taking behaviours, due to new treatment options available or a rising number of migrants, especially from countries with a high HIV prevalence. In 2016 approximately 45% of all newly diagnosed patients were of Swiss nationality, 24% were from other European countries and 9% from countries with a high HIV prevalence. It is assumed that the majority of the HIV positive migrants were infected before their arrival in Switzerland (BAG, 2017d). Projects have been developed using specially trained, cultural-sensitive mediators and social-media activities to reach migrant groups more effectively and to increase testing rates in these groups. In addition the Swiss Red Cross has been supporting the use of media outlets frequently used by migrant groups (SRK, 2017).

1.7 UNITED KINGDOM



In the United Kingdom the number of new HIV diagnoses has been stable over time, but has now significantly decreased in the last year, from 6286 in 2015 to 5164 in 2016. About 0.16% of the population is currently living with HIV. Estimates by Public Health England show that about 12% of persons living with HIV in the UK were not aware of their serostatus, but more than 97% of those diagnosed with HIV were on ART (Table 13).

The main modes of HIV transmission in the UK are through sex between men (46%) and heterosexual contacts (33%), transmission through injecting drug is relatively low (2%).

In 2016 a substantial decline of almost 18% was observed in HIV diagnoses in gay and bisexual men in the UK (Figure 16). In some parts of London, in which the highest testing rates and prompt access to treatment were achieved, the decline in the number of HIV diagnosis was even as high as 29%, indicating the effectiveness of combining prevention and treatment programmes (PHE, 2017a).

The HIV epidemic mainly affects MSM and black African women, but according to Public Health England's 2016 annual report, a great diversity of people living with HIV can be found in the UK. In 2015 the proportion of people diagnosed with HIV who were born in the UK (52%) exceeded the proportion born abroad (48%) for the first time since the 1990s (PHE, 2016a).

Table 13: HIV situation in the United Kingdom

HIV STATISTICS	United Kingdom
General population (in Million) ¹	65.64
Persons living with HIV (2016) ²	106.006
% of PLHIV in the general population	0,16%
90 – 90 – 90 TARGETS³	2016
1st 90: % of PLHIV knowing their status	88%
2nd 90: % of PLHIV diagnosed and on ART	97%
3rd 90: % of PLHIV, ART with viral suppression	97%
NEW DIAGNOSES⁴	2016
New HIV diagnoses	5164
New HIV diagnoses per 100.000 population	7.9
• Male	12.2
• Female	3.7
By mode of transmission²	
• MSM	46.4%
• Heterosexual contact	33.4%
• Injecting drug use (IDU)	2.1%
• Other or undetermined	18.1%

Sources:

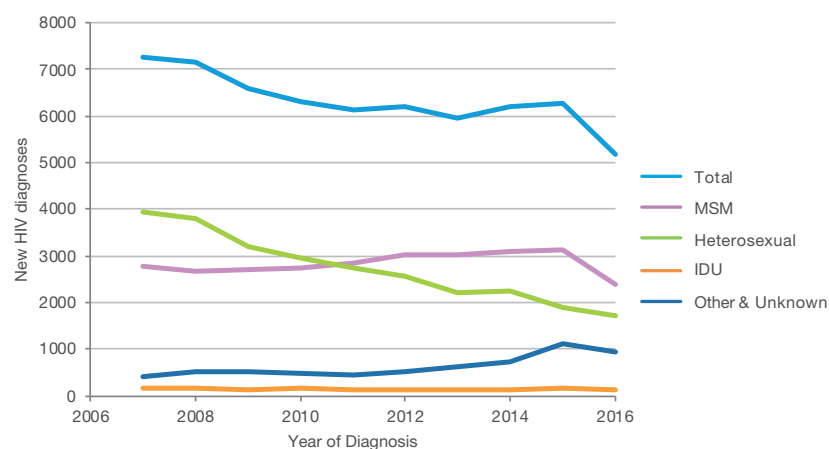
1 World Population Prospects, 2016 Revision, (UNDESA, 2015)

2 HIV testing in England: 2017 report, (PHE, 2017d)

3 Continuum of HIV care, (ECDC, 2017)

4 HIV/AIDS Surveillance in Europe 2017 – 2016 data, (ECDC, 2017e)

Figure 16: New HIV diagnoses, total and by mode of transmission, United Kingdom 2007-2016



Source: HIV/AIDS Surveillance in Europe 2017 – 2016 data, (ECDC, 2017e)

In 2016 more than one million HIV tests were carried out in sexual health services in England and 2358 people with new HIV diagnoses were identified, resulting in a positivity rate of 0.2%. 87% of these individuals were tested in specialist sexual health services, where test coverage was much higher than in non-specialist SHS (68% vs. 28%) (Figure 17).

Figure 17: HIV test offer and coverage in SHS attendees eligible for HIV testing, England 2012 – 2016



Source: HIV testing in England 2017 Report (PHE, 2017d)

¹Eligible SHS attendee: any patient attending a SHS at least once during a calendar year; patients known to be HIV positive or for whom an HIV test was not appropriate, or for whom the attendance was reported as being related to SRH care only are excluded. This includes England residents only.

From 2010 to 2017 HIV testing in specialist sexual health clinics has been increasing steadily, including a 47% increase in HIV testing among gay, bisexual and other men who have sex with men. Results from the “National Survey on Sexual Attitudes and Lifestyles 3” have supported these observations. However they have also highlighted the urgent need to promote testing activities in the MSM and black African communities, especially for those people who perceive themselves to be at high risk of HIV as only 41% (MSM) and 44% (black African) had taken an HIV test in the previous year (PHE, 2016b). The 2017 Public Health England report has re-emphasized the need for better implementation of the annual testing recommendation for high risk groups, mainly MSM and black African men and women (PHE, 2017d).

National HIV Strategy

Public Health England (PHE), an operationally autonomous executive agency of the UK Department of Health, published a strategic action plan for 2016 to 2019 on **Health promotion for sexual and reproductive health and HIV**. The plan complemented the Department of Health's 2013 Framework for Sexual Health Improvement in England and explained how PHE would work towards the outcomes of this and of the Public Health Outcomes Framework (PHE, 2015b).

The vision of the strategic plan has been that PHE and its partners should "ensure that the right actions are carried out for the right people, in the right place, at the right time". Therefore the plan would be addressing the needs of:

- Key population groups, targeting interventions towards those who are at risk of, or are particularly adversely affected by, poor sexual and reproductive health and HIV
- Key geographical areas, delivering appropriate and specific interventions and support to areas with poor sexual and reproductive health and with high levels of HIV infection
- Key life stages, focusing preventative interventions on critical periods of risk in people's lives

PHE would use data, scientific evidence, evaluation and community engagement to work towards the main goals of the strategy:

1. To reduce onward transmission, acquisition and avoidable deaths
2. To reduce rates of sexually transmitted infections
3. To reduce unplanned pregnancies
4. To reduce rate of under 16 and under 18 conceptions

To reduce the burden of HIV infection by decreasing the HIV incidence in populations most at risk and to reduce rates of late and undiagnosed HIV in the most affected communities, PHE would

- Support and facilitate national and local partners to deliver increases in HIV testing in areas of high prevalence (>2:1000) and among populations at heightened risk of HIV
- Facilitate the development and implementation of innovative technologies and interventions for HIV prevention
- Monitor performance through surveillance and reporting of new HIV diagnoses, CD4 count at the time of HIV diagnosis, HIV testing rates, and condom use (PHE, 2015b)

National HIV Prevention Activities

The Terrence Higgins Trust, the largest HIV and AIDS charity in Europe, manages HIV Prevention England (HPE), the national HIV prevention programme for England. HPE delivers a coordinated programme of HIV prevention work, focussing on black African people and MSM, especially in areas of higher HIV prevalence. The programme has been using campaigns, online services, local work and policy work to achieve its goals. It is funded by Public Health England and collaborates with local authorities, NHS clinics and black African, gay and faith communities. HPE has been appointed to deliver five goals (HPE, 2017a):

- Increase HIV testing to reduce undiagnosed and late diagnoses
- Promote condom use as a safer sex strategy
- Promote other evidence-based safer-sex and biomedical HIV prevention interventions
- Raise awareness of the role of STIs in the context of HIV acquisition and transmission
- Reduce levels of HIV related stigma within affected communities and more widely.

HPE uses a social marketing approach, including the “It Starts with Me” campaign, which is being adapted to MSM and African communities, aiming at driving behaviour change by activities on the individual, local, community and “social structural” level. For this campaign and the annual National HIV Testing Week, HPE is working closely with HPA Local Activation s (HPE, 2017c).

PHE has also created the HIV Prevention Innovation Fund to support local, innovative projects across the country, which have the potential to be scaled up or replicated in other areas. Seven projects were funded in 2015 and thirteen projects out of more than 100 applications were shortlisted for the 2016/17 fund, demonstrating an overwhelming engagement from local voluntary sector organisations (PHE, 2017b).

In 2015 PHE published a special action plan for “Promoting the health and wellbeing of gay, bisexual and other men who have sex with men”.

This plan emphasized the importance of not considering sexual health in isolation, but as an area of health interrelating with other areas, including mental health, alcohol and drug use. In addition PHE has been working with the National LGBT Health Partnership, a group of NGOs involved in service delivery both locally and nationally, to support specific projects addressing the wider determinants of inequalities in health and social care affecting the LGBT communities (PHE, 2015a).

The National AIDS Trust, UK’s policy charity dedicated to transforming society’s response to HIV, has published an examination of the UK’s expenditure on primary HIV prevention and HIV testing for 2015/16 and 2016/17. Results from a survey conducted including 230 public bodies across the UK show a decrease in HIV prevention and testing expenditure by about 11% within one year, but high-prevalence areas seemed to have received a greater share of the overall budget. As a significant proportion of community HIV testing services were provided as part of wider HIV prevention contracts, local

authorities were often not able to report detailed expenditure on these. 75% of local authorities reported commissioning HIV testing services, outside of those provided in a sexual health clinic, which was largely due to the high number participating in PHE's National Home Sampling Service (NAT, 2017a).

National HIV Strategy / Policy for HIV Testing

HIV testing policies in England include legal requirements (testing of blood, organ and tissue donors), national antenatal care screening programmes, guidelines by the National Institute for Health and Care Excellence and recommendations by professional societies. These policies are linked to European and WHO recommendations and are aimed at encouraging testing in a wide range of clinical and community settings, geographical areas and risk groups (PHE, 2016b).

The national HIV testing policy has been based on UK testing guidelines introduced in 2008 by the British HIV Association (BHIVA), the British Association for Sexual Health and HIV (BASHH) and the British Infection Society. They advocate routine testing in certain settings, among patients with specific risk factors or diagnosis and according to guidance on organ and blood donation and dialysis. These guidelines recommended expanding HIV testing into primary and secondary care in areas with a high HIV prevalence exceeding 2/1000 local population (aged 15-59 years) (BHIVA, 2008).

The 2008 BHIVA testing guidelines have been supplemented by guidance from the National Institute for Clinical Excellence (NICE) reemphasizing the approach to focus on high-prevalence areas and to increase engagement in MSM and black African populations. NICE has been in charge of developing recommendations for local authorities and partner organisations on promoting HIV testing and on other services to related sexual health (NICE, 2014). Together with Public Health England NICE has published a guideline to increase the uptake of HIV testing in primary and secondary

care, specialist sexual health services and the community, especially among people at higher risk of an HIV infection. NICE has also advocated expanding testing outside clinical settings by engaging community organisations and by providing rapid HIV tests. In addition NICE has been suggesting a move from “opt-in testing” to “opt-out testing” in areas of high or extremely high HIV prevalence (exceeding 5/1000 population; aged 15-59 years), where an HIV test should be routinely carried out for all new patients registering with a General Practitioner, for people attending accident and emergency services, and for those admitted to a hospital (NICE, 2016).

In its 2017 report on HIV testing in England, PHE is highlighting six recommendations (PHE, 2017d):

- 1 Sexual health services** should consider how they can ensure that:
 - All gay and bisexual men are offered and recommended regular (i.e. annual) HIV tests
 - All gay and bisexual men at high risk of HIV acquisition (e.g. a recent anogenital STI diagnosis), are offered and recommended frequent (i.e. every 3 months) HIV tests
 - All black African men and women are offered and recommended regular HIV tests
 - HIV partner notification improves for heterosexuals and gay and bisexual men
 - All other attendees are offered and recommended to have HIV tests
- 2 General practices and secondary care** in high and extremely high prevalence areas should consider how they can ensure that they offer and recommend HIV testing to patients in line with NICE recommendations.
- 3 Commissioners** should consider how they can ensure that people at higher risk of HIV acquisition have access to a range of testing options including community testing and self-sampling.
- 4 Providers of health services** to patients with hepatitis B and C, TB and people who inject drugs should consider how they can ensure that all patients are offered and recommended to have HIV tests.
- 5 Providers of HIV testing in prisons** should consider how they can ensure that HIV testing is implemented and monitored effectively.
- 6 Antenatal service providers and blood, tissue and organ donation services** should continue to maintain current high levels of HIV testing.

Coordination of HIV Testing

The UK Department of Health and Public Health England are in charge of the overall coordination of the national HIV/AIDS strategy, including screening and testing regulation and work closely with a large number of national, regional and local health authorities as well as with HIV civil society organisations. Professional associations and societies such as the British HIV association, the British Infection Society and the British Association of Sexual Health and HIV develop testing guidelines.

The National Institute for Health and Care Excellence (NICE) provides guidance, quality standards and further information on HIV testing and prevention, including NICE Pathways, for regional and local authorities (NICE, 2017a).

The National AIDS Trust, an NGO founded in 1987 by the UK Department of Health, now operates as an independent policy and campaigning charity, providing practical resources to support early diagnosis of HIV through ethical, accessible and appropriate testing among other strategic goals (NAT, 2017b).

Public Health England funds HIV Prevention England, which is managed by an NGO, the Terrence Higgins Trust. This national prevention programme uses campaigns, online services, local work and policy work to improve the uptake of HIV testing, especially among target population groups (HPE, 2017a)

Access

HIV and STI testing in the UK are free, anonymous and available for all. Opportunities in the UK include (PHE, 2016a):

1. Specialist services where all attendees should be offered testing for HIV because they may be at increased risk of HIV:
 - Specialist sexual health clinics (SHCs)
 - Clinical services for TB, hepatitis B and C
 - Drug dependency services
 - Prisons
2. General clinical services where patients should be offered HIV testing depending on the diagnosed HIV prevalence band of their local authority
 - Patients attending general practices
 - Patients admitted to hospitals, including emergency departments
3. Home and community settings, particularly for most at risk groups (gay/bisexual men and black African populations)
4. Services where all attendees should be offered testing for HIV because of the high potential transmission risk to others
 - Antenatal care
 - Blood, tissue and organ donors
5. Self-sampling and self-testing

Target population centres are being used primarily to reach the MSM community and other high-risk population groups in areas with a high HIV prevalence. 56 Dean Street, for example, is an award-winning free HIV and sexual health clinic in Soho, London, run and financed by the Chelsea and Westminster Hospital NHS Foundation Trust. Following a long history dating back to 1862 when the original STI clinic was established, the current site was opened in March 2009 and it is now the UK's largest sexual health clinic accounting for 1 in 9 HIV diagnoses in the UK. In addition to counselling and testing services for HIV and other STIs, full outpatient HIV clinic services are offered. A walk-in service for emergency contraception and emergency appointments is available and there are online services for booking check-up appointments and for ordering free HIV home testing kits. Talking therapies, cultural and social events to enhance the individual's wellbeing and to engage with the community are also organized. 56 Dean Street and its "sister clinics" supply care free to all, regardless of sex, gender, sexuality or lifestyle (56DeanStreet, 2017).

Counselling

Following the 2008 national guidelines for HIV testing, pre-test counselling is no longer a requirement, unless the patient requests or needs this (BHIVA, 2008). All testing centres for HIV and other sexually transmitted diseases offer pre- and post-test counselling services free of charge. The National Health System or the respective provider covers the costs for these services, but funding for these HIV support services were reduced by 28% between 2015/16 and 2016/17 (NAT, 2017a).

Partner Notification

Partner notification has been shown to be effective in diagnosing HIV and clinical services managing patients with HIV or STIs are expected to initiate partner notification as part of HIV management. The National AIDS Trust together with the Society of Sexual Health Advisers (SSHA), BASHH and BHIVA has published national guidelines on partner notification for adults in 2015, defining relevant outcomes and proposing standards. Processes and best clinical practice examples are described in the BASHH Statement on HIV Partner Notification for adults: definitions, outcomes and standards (NAT, 2015).

In 2017 Public Health England observed the highest positivity rates of all HIV testing activities (3.9%) in individuals tested following a notification by their partners. Although the number of notified partners tested in a sexual health service increased by 43% between 2012 and 2016, the overall number of 2211 tested people in 2016 remained comparatively low (PHE, 2017d).

Process

The main HIV tests used in the UK are:

- **4th generation ELISA** (anti-HIV-1 & anti-HIV-2 antibodies, p24 antigen)
- **Rapid point-of-care tests** (HIV-1- and HIV-2-antibodies) followed by a 4th generation ELISA test to confirm a positive result
- **Self-tests** for use by lay persons at home (HIV-1- and HIV-2-antibodies) followed by a 4th generation ELISA test conducted by a health care professional to confirm a positive result

National HIV Testing Guidelines

The UK National Guidelines for HIV Testing 2008, published by the British HIV Association, British Association of Sexual Health and HIV and the British Infection Society, are currently being revised (BHIVA, 2008). Public Health England's National Infection Service has developed UK standards for microbiology investigations for HIV screening and confirmation (PHE, 2017c).

In general HIV testing should be offered under specific circumstances as described by PHE (see page 85). This has been re-emphasized by a quality statement published by NICE in 2017 (NICE, 2017a). In particular MSM are advised to test for HIV and other STIs at least annually or every three months if having sex with new or casual partners. Black African men and women, especially when living in high-prevalence areas, are advised to have an HIV test and a regular HIV and STI screen if having condomless sex with new or casual partners (PHE, 2016a).

The United Kingdom of Great Britain and Northern Ireland legalized the sale of self-test kits in April 2014. During National HIV Testing Week in 2013 and 2014 two programmes provided free HIV self-sampling kits online to use at home. The success of these programmes led to the establishment of a national self-sampling service co-commissioned by Public Health England (PHE) and 89 local authorities (AVERT, 2017a).

The service was launched by PHE for most at-risk populations for HIV acquisition in November 2015. The aim has been to provide a cost effective and clinically robust remote HIV sampling service for sexually active individuals aged 16 years and over especially MSM and black African communities. In February 2016, the service was decentralised with the local authorities taking over responsibility for implementing the service in their areas (PHE, 2016a). During the 2016 National HIV Testing week alone more than 20,000 postal kits were ordered online for free (www.test.hiv) with the majority of orders originating from social media and mobile app advertising (HPE, 2017b).

HIV self-testing has been offered as an additional approach within the UK's HIV testing services. Currently one company, BioSure, holds a regulatory approval to sell HIV self-testing kits and sold more than 25,000 in England between May 2015 and April 2016. The number of tests sold per 1,000 population was considerably higher in extremely high prevalence areas (3.4 tests/1,000) than in high prevalence areas (0.9/1,000) or low prevalence areas (0.7/1,000) (PHE, 2016b). Several studies on the feasibility and acceptability as well as barriers, experiences and impacts of HIV self-testing in the UK are now being conducted and first results have been published (HIVST, 2017c).

Window Period

The British Association for Sexual Health and HIV (BASHH) and the Expert Advisory Group on AIDS (EAGA) published a statement on the HIV window period in 2014. Based on the 2008 UK guidelines for HIV testing the use of the latest 4th generation test (assay test for HIV antibodies and p24 antigen) on a venous blood sample performed in a laboratory is recommended. This test should be offered at 4 weeks after a specific exposure. If a patient attends a testing site already before this date, the test should be offered directly in order to be able to identify an acute HIV infection. This test should then be repeated at 4 weeks after a specific exposure.

As a negative result on a 4th generation test performed at 4 weeks post-exposure is highly likely to exclude an HIV infection, a further test at 8 weeks post-exposure is only recommended in case of a high risk of infection during the reported event. Patients with an ongoing risk of an HIV infection should be advised to retest at regular intervals. Patients should also be advised to have tests for other STIs in line with advice on respective window periods for those infections (BASHH, 2014).

For rapid HIV blood tests, which are recommended for community outreach projects and drop-in clinics only, the window period can be highly variable, PHE suggest that most HIV infections should be detected within 6 weeks of exposure to HIV (PHE, 2017c).

Costs

HIV testing in the UK is universally available and free of charge. The National Health System or private providers (e.g. NGOs) cover the costs.

Expanded HIV testing may be more cost-efficient in acute general medical admission units (ACU) than in general practice (GP) settings as a consequence of a shorter offer time, higher patient uptake, higher HIV positivity and lower diagnostic test costs. A study using data from four Department of Health pilot studies conducted in 2009 and 2010 showed that costs for one HIV test ranged from £ 8.55 (ACU) to £ 13.50 (GP). The cost per new HIV diagnosis was between £ 3230 and £ 5940 in ACUs and £ 7930 and £ 18800 in GP settings (at a positivity of 2/1000 tests conducted). The authors of the study therefore recommend expanding HIV testing in high HIV prevalence areas (Ong et al., 2016).

A cost-effectiveness analysis using a dynamic compartmental model showed that providing annual HIV testing to MSM, injecting drug users and people from HIV-endemic countries, and one-time testing for all other adults, would prevent 4–15% of infections, requiring one-fourth as many tests to diagnose each PLHIV, at a cost of £ 17.500 / QALY gained. The authors conclude that annual HIV testing of key populations in the UK is very cost-effective and that additional one-time testing of all other adults could identify the majority of undiagnosed PLHIV (Long et al., 2014).

A study including 86000 people at 40 GP locations in Hackney, a socioeconomically deprived area in London with an HIV prevalence rate of 8 / 1.000 adults, showed that by offering HIV testing with a rapid test in primary care to all newly registered patients led to a four-fold higher HIV diagnosis rate. A group of researchers examined the data from this research trial using a health economics modelling analysis, including all the costs associated with HIV testing and treatment. Results show that over a 40 year-period, primary care-based HIV screening in high prevalence areas would cost an estimated £26.626 per Quality Adjusted Life Year (QALY) gained and would therefore be cost-effective and life saving. The study authors recommend offering screening to all 74 high HIV prevalence local authorities (>2 HIV infections / 1000 adults) in England (Baggaley et al., 2017).

The number of people needed to be tested to identify one HIV diagnosis varies considerably between different settings. For example, in extremely high prevalence areas 228 people need to be tested in general practices to diagnose one new HIV infection. In comparison to this only 181 people need to be tested in community settings and 139 people through the self sampling service (PHE, 2017d).

Treatment, PEP and PREP

Following a positive HIV test, patients are referred to specialist HIV care teams to identify a personalised package of care, including the initiation and monitoring of appropriate ART. HIV treatment and care is available free of charge throughout the UK. The 2015 guidelines by WHO and the British HIV Association (BHIVA) recommend initiating ART immediately after HIV diagnosis, regardless of the CD4 count to prevent onward transmission (BHIVA, 2015).

The British Association of Sexual Health and HIV published an updated UK guideline for the use of HIV Post-Exposure Prophylaxis following Sexual Exposure (PEPSE) in 2015. Initiation of PEPSE is recommended preferably within 24 hours following an event with a significant risk of HIV transmission, it should be taken for 28 days and follow-up testing is recommended for 8-12 weeks after exposure (BASHH, 2015)

The British HIV Association and the British Association of Sexual Health and HIV are currently developing national guidelines on the use of HIV pre-exposure prophylaxis, which is currently not available through the National Health System (NHS), but can be purchased privately at one of the specialist sexual health clinics or online (BHIVA/BASHH, 2017). In addition up to 10,000 individuals with a very high risk of HIV can be enrolled in a 3-year clinical trial, the PrEP Impact study, funded by the NHS (NHS/PHE, 2017). Interim results from two other studies (PROUD and IPERGAY) have already shown the effectiveness of PrEP in preventing HIV acquisition among at-risk MSM, in combination with condom use (PHE, 2015b). 56 Dean Street, UK's largest sexual health clinic, has reported a 40% decrease in HIV diagnosis in 2016, which doctors at the clinic attribute to an increase in the use of PrEP by HIV-negative people and an early treatment initiation for HIV-positive people in previous years (NAT, 2016).

Policy Evaluations

Public Health England is in charge of monitoring and evaluating UK's testing policies on an ongoing basis. An annual report reviews the implementation of national HIV testing guidelines, addresses national and European recommendations on HIV testing, including in prisons and in other settings. It also presents national HIV testing data collated from national surveillance, sentinel surveillance and national service data.

The report categorizes HIV testing activity into three main settings:

1. 1. Specialist clinical settings where HIV testing is universally recommended
2. 2. General clinical settings where testing is recommended by geographical area: local authority areas with low (<2 per 1,000), high (2-5 per 1,000) and extremely high (≥5 per 1,000) diagnosed HIV prevalence
3. 3. Population groups: at-risk populations including black African men and women, gay/bisexual men, and those with other behavioural or demographic risk factors

Recommendations for action prioritised for different settings and population groups have been published to improve the effectiveness of HIV testing in England (see page 118) (PHE, 2016a).

The National Institute for Health Research has been providing information about ongoing research projects relevant to the HIV testing guidelines published by NICE, e.g. a project to conduct a comprehensive assessment of the cost- effectiveness of HIV prevention and testing strategies, including HIV self- testing, among MSM in the UK (NICE, 2017b).

Good Practice Examples

In the UK a substantive decline in HIV diagnoses in gay and bisexual men has recently been observed indicating the effectiveness of combining prevention and treatment programmes. It is assumed that the decline is driven by large increases in HIV tests among gay and bisexual men attending sexual health clinics (from 37,224 in 2007 to 143,560 in 2016), repeated testing in higher risk men, by improvements in the uptake of anti-retroviral therapy following HIV diagnosis, sustained high condom use with casual partners as well as access to pre-exposure prophylaxis through online purchasing (PHE, 2017a).

NICE has been using surveillance data and research results to develop up-to-date guidelines, for example, to increase uptake of HIV testing among people who are unaware of their HIV infection in primary and secondary care, specialist sexual health services and the community. Other special guidelines have been focussing on MSM and black African communities (NICE, 2016).

56 Dean Street, a target population centre has won numerous awards for its comprehensive testing, counselling and treatment services. In addition the centre is involved in a number of cultural and social events to enhance the individual's wellbeing and to engage with the surrounding community (56DeanStreet, 2017).

Challenges

The number and proportion of diagnoses made at a late stage of an HIV infection remain high in the UK, especially in heterosexual men (60%) and women (47%), compared with only 32% in gay and bisexual men. This factor is associated with a higher risk of mortality and an increased risk of onward transmission (PHE, 2017a).

Studies have also shown that HIV prevalence among black Africans living in the UK is comparatively higher than in the general population. For example, nearly 18 out of 1.000 black African heterosexual men and nearly 44 out of 1.000 black African women were living with HIV in 2014 compared to 0.5 per 1.000 non-black African men and nearly 1 per 1.000 non-black African women. The African Health and Sex Survey 2013/2014 with more than 1000 participants, of which 10.9% were HIV positive, showed an overall annual HIV testing rate of just 36.8% in this group and 35% of the respondents had never been tested for HIV (AVERT, 2017a).

A 2015 report by the Family Planning Association (FPA) showed that HIV-related stigma and discrimination remain major barriers to testing and linkage to care and prevention efforts. With its ongoing **UK Stigma Index** FPA aims to find out more about these problems affecting people living with HIV in their daily lives (FPA, 2017).

A research study on **The future of HIV services in England** conducted by the King's Fund argued that a fragmented system for HIV care had been created through the 2012 Health and Social Care Act. As responsibilities for delivering services continue to be spread between NHS England, local health organisations and councils co-ordinated changes across separate HIV services have been difficult to implement (Baylis A, 2017).

2. OVERVIEW OF POLICIES AND TESTING ASPECTS

	France	Germany	Netherlands	Portugal	Sweden	Switzerland	UK
Documents (Year)							
National HIV Strategy	2010-2014	2016	2012-2016	2017-2020	2006-2016	2011-2017	2016-2019
National Policy on HIV testing	2008-2009	N/A	N/A	2017-2020	N/A	N/A	2016
National HIV testing guidelines (latest update)	2017	N/A	2014	2014	2015	2013	2016
HIV testing guidelines issued by professional society		2015	2017				2008
Main Target Groups							
• MSM	✓	✓	✓	✓	✓	✓	✓
• Injecting drug users	✓	✓	✓	✓	✓	✓	✓
• Migrants from high-prevalence countries	✓	✓	✓	✓	✓	✓	✓
• Sex workers (and clients)	✓	✓	✓	✓	✓	✓	✓
• Prisoners		✓		✓		✓	✓
• General Population	15-70 y.			18-64 y.	Travellers ³	✓	Black African
• Youth			✓		✓		
Testing: Access							
• HIV Target Group Testing Centres (examples)	CeGIDD / TROD	Checkpoints	STI clinics	CheckpointLX	Checkpoints	Checkpoints	56 Dean street
• Routine offering by General Practitioner	Yes	No	No	Yes	No	No	No ⁷
• Routine offering in emergency departments	Yes	No	No	Yes	No	No	No ⁷
• Non-medical settings (Community-based)	Yes	Yes	Yes	Yes	Yes	Yes	Yes
• Self-testing permitted	Yes	No	Yes	No	No	No	Yes

2. OVERVIEW OF POLICIES AND TESTING ASPECTS

	France	Germany	Netherlands	Portugal	Sweden	Switzerland	UK
Testing: Process							
• Confidentiality	Yes	Yes	Yes	Yes	Yes / No ⁴	Yes	Yes
• Opt-in / Opt-out	Opt-out	Opt-in	Opt-in & Opt-out	Opt-out	Opt-in & Opt-out	Opt-in	Opt-in & Opt-out
• Anonymous testing	Available	Available	Available	Available	Available	Available	Available
• Conducted also by lay providers	Yes	Yes	Yes	Yes	Yes	Yes	Yes
• Post-test access to treatment, care and prevention services	Yes	Yes	Yes	Yes	Yes	Yes	Yes
• Multi-disease testing routinely offered in	STI clinics	STI clinics	STI clinics	STI clinics & GAT ²	STI clinics	STI clinics	STI clinics
Testing: Counselling							
• Pre-test counselling	Yes	Yes	Yes	Yes	Yes	Yes	Voluntary
• Post-test counselling	Yes	Yes	Yes	Yes	Yes	Yes	Yes
• Assisted partner notification available	No	No	Yes	Yes	Mandatory	No	Yes
• Window period (Laboratory / rapid test)	6 weeks / 3 months	6 weeks / 12 weeks	3 months / 3 months	3 months / 12 weeks	6 weeks / 8 weeks ⁵	3 months / 3 months	4 weeks / 6 weeks
Treatment							
• ART begin	ASAP	ASAP	ASAP	ASAP	ASAP	ASAP	ASAP
• ART available for	All ¹	All	All	All	All	All ⁶	All
• PEP	Free	Free	Free	Free	Free	Self-paid	Free
• PrEP	Free	Self-paid	Self-paid	Self-paid	Self-paid	Self-paid	Self-paid

1 France: Some migrants are excluded from this policy

2 Portugal: An NGO-led project is aiming at implementing a service for early diagnosis of HIV, HBV, HCV and syphilis

3 Sweden: HIV testing should be offered to people within six months following their return from a country with a generalized HIV epidemic

4 Sweden: Infections with HIV, syphilis, chlamydia, gonorrhoea, hepatitis B and C are notifiable. It is compulsory for healthcare providers to initiate partner notification, for index patients to accept partner notification and for partners to undergo testing and, if indicated, treatment.

5 Sweden: If a HIV-2 exposition is suspected, a 12-week window period is recommended for both 4th generation laboratory tests and rapid response tests.

6 Switzerland: Some patients are required to pay deductibles and co-payments. Migrants might only have restricted access to HIV treatment.

7 UK: HIV tests should routinely be offered by general practitioners and in emergency departments in areas with a high (2-5 per 1,000) and extremely high (≥5 per 1,000) HIV prevalence rate.

3. BRIEFINGS ON SPECIFIC HIV TESTING ASPECTS

- 3.1 Towards universal voluntary counselling and testing
- 3.2 Enhancing Provider initiated testing and counselling
- 3.3 Considering Multi-Disease testing in the HIV context
- 3.4 Self-testing – a promising tool in the fight against HIV/ AIDS
- 3.5 HIV testing services for migrants
- 3.6 Finding the right window period
- 3.7 Supporting partner notification
- 3.8 Reviewing the cost effectiveness

3.1 TOWARDS UNIVERSAL VOLUNTARY COUNSELLING AND TESTING

In most countries a variety of **voluntary HIV counselling and testing (VCT)** opportunities have been offered. Facility-based HIV testing remains essential. Community-based testing services need to be expanded to meet national and global targets and to reach key population groups.

The **promotion of VCT services** is essential for a successful response to the HIV epidemic and in the fight against other STIs. Individuals, who want to know their HIV status, can actively seek out these VCT services. They are offered by a range of governmental and non-governmental providers and conducted by professionals (doctors / nurses) or lay people, who are specially trained. In most settings a 4th generation rapid test is used, sometimes combined with tests for other STIs. Benefits can be gained through VCT services at the individual level (e.g. reducing risk, improving access to care), community level (wider knowledge, collective action) and population level (reduction of stigma and discrimination).

Despite the numerous current programmes and campaigns the proportion of undiagnosed people living with HIV remains high in many European countries. It has been estimated that on average about **15% of people living with HIV in the European region are unaware of their serostatus**. Socioeconomic, legal and regulatory barriers, especially to community testing and self-testing, prevent many of these people from being tested and treated.

In France rapid diagnostic tests for orientation (Test Rapide d'Orientation Diagnostique; TROD) have been used to increase screening activities and earlier detection of HIV especially in target groups (homo- and transsexuals, migrants, sex workers and IDUs). The provision of these rapid tests in community settings has helped to reach individuals with a high risk of exposure to HIV, who often had not previously used or have not had direct access to the health care system. An increase in the number of screening tests from 4.400 in 2011 to 56.500 in 2013 and the strong increase observed in the percentage of positive test results from 1.05% in 2012 to 8.6% in 2013 have shown the effectiveness of this approach (FRA, 2015).

In the **Netherlands** a specific regulation (Aanvullende Seksuele Gezondheidszorg (ASG)) was introduced in 2009 to provide **low-threshold and free of charge STI/HIV testing and care for high-risk groups** (esp. MSM) at Centers of Sexual Health. Special GP centres, supported by the STI centers have also been established for asylum seekers (RIVM, 2011). The costs for the STI centers under the ASG regulation have increased in recent years. Following an evaluation of this approach a financial ceiling has been imposed and certain risk groups have been excluded from the programme (RIVM, 2014a).

Since the introduction of rapid tests in **Portugal** community-based organizations have become key partners to national health services in the area of testing for HIV / AIDS, viral hepatitis and other STIs. Under the umbrella of a GAT led project (Rede de Rastreio) a **community based screening network** has been established, aiming at implementing a service for early diagnosis of HIV, HBV, HCV and syphilis and at collecting and reporting data for epidemiologic surveillance of hard-to-reach populations. The project has been complementing services provided by the formal health system ensuring appropriate linkage to care (RDR, 2017).

In **Switzerland** a range of providers offers VCT services for HIV and other STIs. These providers are required to follow the **Swiss national VCT guidelines** to guarantee the highest possible standard. These include systematic documentation of a risk analysis and counselling prior to and following tests. The Federal Office of Public Health has developed a **web tool, BerDa**, to ensure a high level of counselling quality in VCT centres. This is based on a self-administered questionnaire, creating a risk profile for the person requesting the test. BerDa offers a structure for the consultation and a series of targeted recommendations relevant to the answers provided and to the client's sexual behaviour (BAG, 2011b).

In the **UK** the National Institute for Clinical Excellence (NICE) has also advocated expanding testing outside clinical settings by engaging community organisations and by providing rapid HIV tests. A study by Public Health England has shown that in community settings in extremely high prevalence areas **181 people needed to be tested to identify one HIV diagnosis** (vs. 228 in general practices and 139 through the self sampling service) (PHE, 2017d).

The overall cost of a testing procedure for one patient in a community-based setting differs considerably between countries. In a community-based setting in Lisbon this is around € 75 (vs. € 40 in Athens and € 100 in Paris). The cost per reactive test is about € 2200 in Lisbon (vs. € 2000 in Athens and € 6200 in Paris). The authors of the study conclude that **community-based services detect a high number of HIV cases at a relatively low cost in many European countries** and therefore should be recommended for early detection of HIV and fast linkage to care (Perelman et al., 2017).

Other countries

In **Norway** a cross-sectional study of an HIV testing service for MSM (Sjekkpunkt Norway) indicates that a **low-threshold testing service** can reach important target groups, including hard to reach groups like MSM with non-western immigrant backgrounds, by combining outreach testing activities in traditional gay venues as well as in more neutral locations, which are not associated with LGBT communities or organisations (Moseng and Bjørnshagen, 2017).

A scoping review investigating **HIV Point-of-Care Testing** services in **Canada** showed that this approach was feasible and had been accepted and preferred to conventional HIV testing services by diverse population groups in Canada. Users have been highly satisfied with the testing process and follow-up and linkage to treatment and care were also good (Minichiello et al., 2017). The **Vancouver Seek and Treat for Optimal Prevention of HIV/ AIDS (STOP) Project** started was started in 2010 by the city of Vancouver, Vancouver Coastal Health and Providence Health Care and has been funded by the Ministry of Health. Combining a routine offer of HIV testing (in family practice and acute care) with a risk-based testing approach (targeting high prevalence populations) marked a fundamental, strategic shift. Both approaches have shown to be increasing HIV testing and detection rates and have proven to be cost-effective (Johnston, 2013).

An examination of the **community-based HIV testing service RAPID** in Queensland, **Australia**, showed that hard-to-reach groups could be increasingly reached by using innovative strategies including rapid HIV testing

in community and outreach settings and by engaging peer service providers. The majority of individuals tested in the studied period were urban-based gay men, 17.1% were first-time testers and 20.1% of participants were not eligible to access Australia's universal health care scheme (Medicare). The implications for the ongoing treatment and care of people, who test positive to HIV, but are not ineligible for Medicare required careful consideration (Mutch et al., 2017).

Operational knowledge to improve HIV early diagnosis and treatment among vulnerable groups in Europe

The purpose of the **HIV-COBATEST project** (2009 – 2017) was to generate operational knowledge to understand the role and impact of **Community Based Voluntary Counselling and Testing (CBVTC)** services better, to explore the use of innovative strategies based on new technologies and to increase early HIV/STI diagnosis and treatment in Europe among the most affected groups. The project aimed to generate harmonized monitoring and evaluation data from CBVTCs across Europe and to explore the acceptability, feasibility and effectiveness of innovative strategies, like Point of Care technologies for HIV and STI diagnosis, HIV self-testing and web based outreach and counselling approaches. Information was obtained about patterns and determinants of test seeking behaviours among MSM and about barriers to access diagnosis and care for migrants. A toolkit for the implementation of checkpoints specifically addressed to MSM and web based applications to deliver test results and counselling, have also been developed. The **COBATEST Network** now links community-based voluntary counselling and testing services in 21 countries across Europe (www.cobatest.org).

A systematic review and meta-analysis of voluntary HIV counselling and testing services showed that community-based testing outside of health facilities achieved high rates of uptake, reached people with high CD4 counts, and linked people to prevention, treatment and care. As costs for these services appear to be similar to those of facility-based HIV counselling and testing services, the authors of the analysis recommend offering community-based testing in addition to facility-based testing (Suthar et al., 2013).

Recommendations

WHO: In all HIV epidemic settings, community-based HIV testing and counselling for key populations, with linkage to prevention, care and treatment services is recommended, in addition to provider-initiated testing and counselling (strong recommendation, low-quality evidence) (WHO, 2013).

WHO Regional Office for Europe: Member States are encouraged to expand targeted HIV testing by focusing on key populations in settings with a high HIV prevalence, to ensure an early linkage to treatment, care and prevention services and to promote rapid HIV testing. These aims could be achieved by the testing of target populations through community and outreach services and lay service providers as well as through testing in closed settings and self-testing (WHO/EURO, 2016).

Expanded access to voluntary and confidential counselling and testing is essential for an effective HIV prevention strategy.

(UN Declaration of Commitment on HIV/AIDS, 2001)

3.2 ENHANCING PROVIDER INITIATED TESTING AND COUNSELLING

Provider initiated testing and counselling (PITC) remains vital for the response to the HIV epidemic as it helps to normalize the HIV testing process, leading to higher testing coverage and earlier diagnosis. Physicians, especially general practitioners, need to be trained to recognize HIV risk factors and indicator conditions to be able to offer appropriate counselling and testing to individual patient.

In the **PITC** approach, a health care provider recommends HIV testing and counselling to persons attending health care facilities as a standard component of medical care (e.g. for patients with a high risk of an HIV infection, patients with symptoms indicating a possible HIV-infection, patients with STIs or during pregnancy). The PITC approach varies between countries. Some countries mainly use an **opt-in approach**, where patients are being offered to be tested for HIV, requiring their explicit consent. Other countries are applying an **opt-out approach**, where patients are informed that HIV testing will be performed as part of their care, unless they explicitly decline (see table 14)

Traditionally most countries have used an opt-in approach only, but more and more countries are now using an opt-out approach or a combination of both. The routine offer of an HIV test by general practitioners or in emergency departments to every patient independent of their risk or to patients from specific risk groups as well as to patients with signs and symptoms indicating a possible HIV infection (**Indicator condition-guided testing**) has proved to be a feasible approach. However, this is very much dependent on the respective health system, the societal and geographical context and cost-effectiveness also needs to be taken into serious consideration.

An **ECDC** evaluation showed that in 2017 35% of national testing guidelines in the participating countries recommended offering HIV testing in general practice settings, but only 17% in emergency departments. In addition 48% of ECDC Member States reported the inclusion of indicator-condition guided HIV testing into their national testing guidelines (ECDC, 2016b).

France has been successfully using an opt-out policy, offering HIV testing to **all individuals between 15 and 70 years** of age independent of their risk exposure when they are using the health care system. Results have shown that this HIV screening of the general population is cost-effective, when offered once in a lifetime or even once every 10 years (HAS, 2017b).

Table 14: PITC approach used in the countries studied

Country	Opt-in	Opt-in / Opt-out	Opt-Out	General population group targeted
France				15 - 70 years (once)
Germany				
Netherlands				High-risk groups, high prevalence areas
Portugal				18 – 64 years
Sweden				International travellers
Switzerland				
UK				Black Africans, high prevalence areas

In **Portugal** an opt-out strategy is now used and laboratory testing for HIV has been recommended for **all individuals between 18 and 64 years** when accessing the health system at least once. In addition a non-reactive test has been repeated in different subpopulations regardless of age (e.g. in persons with signs and symptoms indicating a possible HIV infection, persons with an STI, MSM, IDUs, migrants from high-prevalence countries etc.). By recommending an opt-out strategy the Portuguese authorities aim at ensuring earlier diagnoses and linkage to treatment, preventing further spread of the disease, and reducing the number of new-borns infected with HIV. In addition the reduction of stigma and discrimination associated with taking an HIV test could be reduced (DGS, 2014).

In the **Netherlands** an “**active testing policy**” has been applied since 2002, encouraging GPs to offer HIV and STI tests to people from high-risk groups and to those who come from high-prevalence countries (RIVM, 2016). A comprehensive study on HIV testing strategies in primary care and other healthcare settings in the Netherlands, concluded that **HIV indicator condition-guided testing by GPs has been essential for a more proactive HIV testing approach** (Joore, 2017). In addition routinely offered HIV testing to all patients living in areas where HIV prevalence is higher than 2 per 1000 population is being discussed (SOAIDS, 2017a).

In the **UK** similar experiences have been reported and NICE has suggested a **move from “opt-in testing” to “opt-out testing”** in areas of high or extremely high HIV prevalence (exceeding 5/1000 population; aged 15-59 years). Here an HIV test should be routinely carried out for all new patients registering with a General Practitioner, for people attending accident and emergency services, and for those admitted to a hospital (NICE, 2016).

In **Sweden** HIV testing is to be offered to **all international travellers** within six months following their return from a **country with a generalized HIV epidemic**. According to the “Health and Medical Care for Asylum Seekers and Others Act” county councils should also offer a health examination to all **migrants** within two months of arriving in Sweden, including a voluntary screening for HIV. The proportion of migrants and asylum seekers taking this health examination has varied considerably between the Swedish counties (SWE-GOV, 2012).

Germany has been using an **opt-in policy**, but is now discussing new approaches to HIV testing. According to the Federal Ministry of Health patients (esp. young people, MSM, IDUs and prisoners) have often not been informed sufficiently about HIV and STI counselling, testing and treatment services. In addition these services were still unavailable in some regions with high-prevalence rates of STIs (GER, 2016).

Switzerland has been using a PITC approach, where physicians offer an HIV test to patients, when **indicator conditions** have been detected, STIs or tuberculosis were diagnosed or when risky behaviour was reported. The Federal Office of Public Health has published **special guidelines for PITC**, developed by the Swiss Federal Commission for Sexual Health (FOPH, 2015).

Other countries

The **US Centre for Disease Control and Prevention** (CDC) recommends HIV testing to be offered to **all individuals between the ages of 13 and 64** years at least once in their lifetime as part of their routine health care. People with risk factors for HIV should get tested at least annually. Specific guidance for provider initiated testing and counselling in primary care, hospital and emergency departments as well as in other settings has been published (CDC, 2017b).

In a study in **Canada** the available scientific evidence to determine if routine HIV testing in primary care settings improved HIV testing outcomes has been reviewed. Results show that offer rates varied, but were generally higher when an opt-out approach was used. Acceptance rates also varied between 35% and 89%, but most of the studies reviewed showed an increase of the absolute number of tests performed. Strong evidence was found in relation to the successful identification of people living with HIV through routine testing programmes, with rates above the cost-effectiveness threshold of 0.1% (Broeckaert, 2017).

The **OptTEST project** (Optimising testing and linkage to care for HIV across Europe) was a 3-year project co-funded by the EU Commission (2014 – 2017). The project was run by the HIV in Europe initiative and produced tools and assessment methods to analyse and effectively respond to late presentation for HIV care and treatment, with a particular emphasis on priority regions and groups. As part of the project barriers to early HIV diagnosis, including institutional and health care provider level barriers (accessibility of testing facilities, laws and regulations, stigma and discrimination, reluctance to offer the test) as well as patient level barriers (such as perceived low risk or fear of positive result) were identified. The authors of the OptTEST's final report call for increasing early HIV diagnosis by implementing PITC when individuals with indicator conditions present to health care settings and strengthening PITC in other health care settings for key populations (HIV-in-Europe, 2017c).

Indicator condition-guided testing

A review of national speciality guidelines for HIV indicator diseases conducted in **Spain, UK and Estonia** showed that many of these guidelines did not recommend HIV testing. Therefore general practitioners and medical specialists managing indicator-guided conditions might be unaware of the importance of testing the patient for HIV, leading to a missed opportunities to diagnose the individual earlier. The authors of the review concluded that indicator condition guided HIV testing is acceptable and feasible and is an important part of the strategy to disrupt HIV transmission and promoting earlier diagnosis (Lord et al., 2017).

Another study analysed the impact of IC-guided testing on clinics' HIV testing rates in a number of European countries (e.g. **Czech Republic, Estonia, France, Greece, Poland, Spain and UK**). A range of tools and interactive service design modules have been developed to support the implementation of indicator condition guided HIV testing in the clinics. These simple tools have proved to be successful, **significantly increasing testing offers (by 66%) and testing rates (by 102%)** in general and clinical practice, including emergency departments (Sullivan, 2017). A range of information material and tools to support the implementation of indicator condition guided HIV testing has been offered by the OptTest project (OptTEST, 2017).

The **HIV in Europe initiative** published guidance for implementing HIV testing in adults presenting with indicator conditions in healthcare settings. **Policy makers are encouraged to include indicator condition-guided testing into national HIV testing strategies**, approaches and practical tools for education and training of healthcare professionals have been suggested. HIV testing should be offered in any healthcare setting to any person from key population groups (e.g. MSM, IDUs, sex workers and their clients, migrants from high-prevalence countries, patients with STIs etc.) (HIV-in-Europe, 2012).

Recommendations

WHO: For countries with a low HIV prevalence, WHO promotes the PITC approach, where providers in health-care settings assess the individual's risk factors for HIV and routinely offer testing to those who have been or who are still potentially exposed to HIV as well as to those presenting with HIV indicator conditions.

WHO and **UNAIDS** published special guidelines for PITC in health facilities, **suggesting the use of an opt-out approach even for countries with a concentrated epidemic.** A supportive social, policy and legal framework should be ensured and HIV testing should be offered to all who present to health facilities with signs and symptoms indicating a possible infection with HIV. PITC should be closely linked with prevention, treatment, care and additional support services (WHO, 2007).

ECDC recommended including HIV testing in any national policy for the prevention and treatment of HIV or other STIs, viral hepatitis, tuberculosis as well as other HIV indicator diseases. HIV testing should routinely be offered to all individuals presenting with indicator diseases (ECDC, 2010a).

Indicator condition guided HIV testing is acceptable and feasible and is an important part of the strategy to disrupt HIV transmission and promoting earlier diagnosis.

(Lord et al., 2017)

3.3 CONSIDERING MULTI-DISEASE TESTING IN THE HIV CONTEXT

Sexually transmitted diseases and other HIV co-infections remain of critical importance in the response to the HIV epidemic. **Multi-Disease testing** has the potential to increase detection rates, allowing earlier linkage to treatment and care and reducing the risk of further transmission.

The risk factors, transmission routes and clinical symptoms of an HIV infection are often similar to those of other **sexually transmitted diseases**, such as **syphilis, hepatitis B and C, chlamydia, gonorrhoea and HPV**. As the true prevalence of these diseases is largely underreported, with many cases going unscreened and undetected, regular screenings for STIs, coupled with that of HIV, remain essential in a comprehensive approach to sexual health.

HIV co-infections, especially with **tuberculosis**, are of major concern. Between 2011 and 2015 new HIV/TB co-infections increased in the WHO European region by 40% with persistently high rates of drug-resistance tuberculosis. This increase is mainly due to increasing numbers of infections in non-EU/EEA countries but due to migration trends TB (tuberculosis) elimination remains a major challenge for all countries.

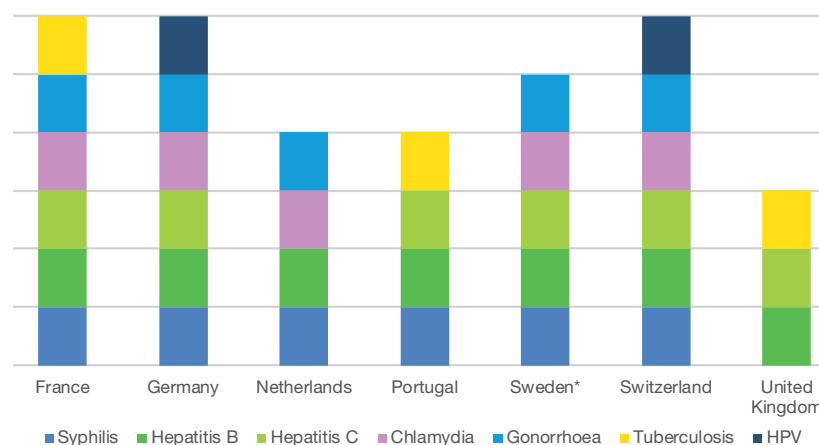
Many countries have connected their response to the HIV epidemic with their strategies and policies for sexually transmitted diseases and tuberculosis. HIV and / or STI testing services offered in different settings vary, although some linkages can be seen depending on the respective epidemiological situation. Policy makers and public health authorities are searching for synergies, e.g. through multi-disease testing opportunities, to increase the uptake and efficiency of testing services.

Among the main goals of the **French National Plan to combat HIV/AIDS and sexually transmitted diseases** are the reduction of gonorrhoea and syphilis incidence, chlamydia and HSV prevalence as well as the reduction of HPV incidence and prevalence. Anonymous testing for HIV, viral hepatitis and other sexual transmitted infections has been widely offered free of charge in special community-based testing centres as well as in some authorized family planning or mother and child centres (FRA, 2016).

The **German** Federal Government published an **Integrated strategy for HIV, hepatitis B and C and other sexually transmitted diseases** in 2016, which is based on a demand-orientated and cross-sectoral concept. The strategy emphasizes the vital importance of testing services, closing the gap between prevention and care not only for HIV, but also for other sexually transmitted and blood-borne diseases (hepatitis B and C, syphilis, gonorrhoea, chlamydia, HPV) (GER, 2016)

Since 2002 the **Dutch National Policy Plan for STI/HIV** has been based on an “active testing policy”. This has included antenatal screening for pregnant women and the integration of testing aspects into the STI/HIV-protocol for GPs, encouraging them to offer HIV and STI tests to people from high-risk groups and to those who come from high-prevalence countries (RIVM, 2016). In 2009 a specific regulation (ASG) was introduced to provide low-threshold and free of charge STI/HIV testing and care for high-risk groups at Centres of Sexual Health. The main STIs being targeted in relation to HIV in the Netherlands are chlamydia, syphilis, gonorrhoea and hepatitis B (RIVM, 2011).

Figure 18: HIV co-infections specifically mentioned for consideration in key national HIV/AIDS strategy / policy documents



*Sweden does not have a national HIV/STI testing strategy. Swedish counties have implemented regional HIV/STI programmes. HIV, Syphilis, Chlamydia, Gonorrhoea, Hepatitis B and C are notifiable diseases and partner testing is mandatory

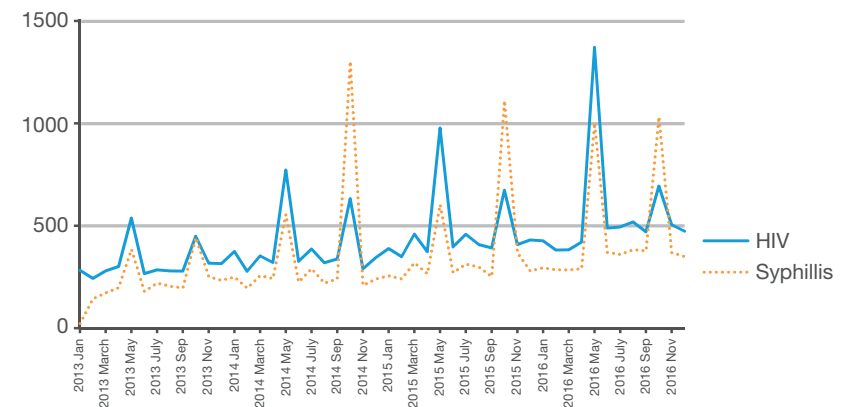
In **Portugal** a specific objective of the National HIV / AIDS Prevention and Control Programme has been the promotion of the **combined detection of HIV, other STIs, viral hepatitis and TB** by increasing the capacity of testing centres (POR, 2011). As part of this programme a range of projects led by 17 NGOs have been developed for vulnerable populations. For example the **community screening network** (Rede de Rastreio Comunitária), which reaches out to migrants, IDUs, MSM and sex workers provides an **early detection system for HIV, hepatitis B and C as well as syphilis** (e.g. MOVE-SE in Setúbal district) (GAT, 2017a).

The majority of Swedish counties have implemented regional HIV/STI programmes based on the national guidance documents published by the Public Health Agency of **Sweden**. Voluntary counselling and testing for HIV and other STIs is available for free and in general an **opt-in approach** is used. In case of a positive test for one of the notifiable diseases (HIV, syphilis, chlamydia, gonorrhoea, hepatitis B and C) partner notification must be initiated and testing of those partners is mandatory (Folkhälsomyndigheten, 2015c).

In the **UK's national HIV prevention programme** one of the main goals is raising awareness of the role of STIs in the context of HIV acquisition and transmission (HPE, 2017a). MSM are advised to test for HIV and other STIs at least annually or every three months if having sex with new or casual partners. Black African men and women, especially when living in high-prevalence areas, are advised to have an HIV test and a regular HIV and STI screen if having condomless sex with new or casual partners (PHE, 2016a). HIV testing has also been carried out among people attending with **HIV clinical indicator conditions**. In 2016 93% of people notified with TB in the UK were tested for HIV, and 3.8% of TB cases were co-infected with HIV. Between 2010 and 2014 less than 50% of people diagnosed with hepatitis B and C were tested for HIV within 6 months of their diagnoses (2.4% and 1.9% respectively were tested positive for HIV) (PHE, 2017d).

The **Swiss National Programme for HIV and other Sexually Transmitted Infections** covers all issues concerning prevention, diagnosis and treatment of HIV and other STIs, including chlamydia, syphilis, gonorrhoea, hepatitis, HPV, lymphogranuloma venereum and herpes (FOPH, 2011). Since 2012 the Federal Office of Public Health has strongly encouraged the VCT approach for HIV and other STIs and the implementation of the "Break the Chains" campaign, aiming at interrupting the HIV transmission chains among MSM by encouraging them to get tested for HIV in May every year (Frey et al., 2014). This campaign has been closely linked to the STOP SYPHILIS campaign, in which guidance and free testing for syphilis and other STIs has been offered annually during the month of October (AIDS-Hilfe, 2013). An analysis has shown the success of both campaigns, which are effectively complementing each other (Figure 19).

Figure 19: Number of HIV and Syphilis tests conducted in VCT centres per month, 2013 - 2016



Source: Swiss Federal Office of Public Health, Bulletin 43/17, (BAG, 2017d)

In **Canada**, tests for other STIs, hepatitis B and C and tuberculosis as well as a comprehensive HIV/STI risk assessment are recommended for all patients who have been tested positive for HIV (CAN, 2017). The Centers for Disease Control and Prevention in the **United States** have been promoting programme collaboration and service integration to enhance the prevention and control of HIV/AIDS, viral hepatitis, STIs and TB. New CDC recommendations, advances in diagnostic technology and routine HIV testing in clinical settings as well as in other settings have greatly decreased barriers and facilitated the provision of integrated services. In addition it is evident that offering e.g. hepatitis vaccination may increase acceptance of STD and HIV testing and other prevention services (CDC, 2009). While many countries have conducted a number of multi-disease prevention and testing campaigns in response to their specific epidemiological HIV situation, clear recommendations for multi-disease testing are rare and combined testing devices are currently not widely used or recommended.

News

Unitaid published a **landscape report**, profiling more than **95 multi-diseases testing devices**, which are on the market or in development, addressing a range of key disease areas such as HIV, hepatitis C, tuberculosis and malaria. The authors of this report believe that the implementation of multi-disease diagnostic platforms, which can sequentially or simultaneously test for multiple infectious agents, pathogen variation and AMR, could streamline and simplify infectious disease diagnosis and management and could become an essential step in the quest to end these pandemics (UNITAID, 2018).

e-STI testing

Internet-accessed sexually transmitted infection testing (e-STI testing) has increasingly become available. It enables users to order a test kit from a website or app, collect their own samples, return test samples to a laboratory and be notified of their results by short message service (SMS) or telephone. A randomised controlled trial has been conducted in London with more than 2000 participants to assess the effectiveness of an e-STI testing and results service (for chlamydia, gonorrhoea, HIV, and syphilis). Results show that this e-STI testing service increased uptake of STI testing for all groups including high-risk groups. According to the authors of this study service innovations to improve treatment rates for those diagnosed online and long-term monitoring and evaluation of e-STI of services are necessary (Wilson et al., 2017).

Recommendations

WHO believes that offering multi-disease HIV testing campaigns in addition to other health services such as screening for STIs, hepatitis, cardiovascular risk factors, diabetes, hypertension or depression can be beneficial for public health, especially in low- and middle-income countries with high prevalence rates for infectious diseases. At the present time WHO does not explicitly recommend multi-disease testing campaigns for routine use in countries with concentrated HIV epidemics. This has been due to a lack of assessments concerning the cost-effectiveness and the long-term impact of the additional services provided. Further studies and evaluations would be required (WHO, 2015a).

WHO has suggested considering the use of multi-disease testing devices for TB, HIV and hepatitis in integrated laboratory networks. This would provide new opportunities for collaboration and integration leading to significant system efficiencies and cost savings, increasing patient access as well as improved quality of care (WHO, 2017d). WHO has also published an information note on the use of dual HIV/syphilis rapid diagnostic tests providing interim advice for countries using or planning to introduce this prequalified device in antenatal services and other testing sites. This note has emphasized the need for both ensuring the quality of HIV and syphilis testing using RDTs and laboratory-based testing (WHO, 2017e).

ECDC recommends that any national strategies for the prevention and treatment of HIV, other STIs, viral hepatitis, tuberculosis and other HIV indicator diseases must include HIV testing. Moreover testing for STI and viral hepatitis should be offered together with HIV testing for population groups at higher risk (ECDC, 2010a).

3.4 SELF-TESTING – A PROMISING TOOL IN THE FIGHT AGAINST HIV/AIDS

HIV self-testing and self-sampling are promising innovative approaches to encourage people who want to know their status but prefer a confidential test. These approaches should be made available in addition to other facility- or community-based HIV testing services.

HIV self-testing is when a person administers the HIV test himself / herself, interpreting the results in private and HIV self-sampling is when a person takes the sample (saliva or blood) and mails this to a laboratory. Both practices are becoming more common. Appropriate and adequate instructions for use of the HIV self-test kits are essential to reduce errors and maximize the accuracy. Clear and concise instructions – written and pictorial – are critical to ensure correct use and interpretation. In particular users need to understand that a positive test result must be confirmed through laboratory-based testing. A referral system for people who test positive needs to be ensured, including access to confirmatory testing, counselling, treatment and care.

Despite the progress that has been made in many areas related to HIV / AIDS, such as increasing awareness, reducing stigma and discrimination or offering low-threshold testing facilities for target groups, some challenges and barriers still remain for individuals wanting to know their HIV status. HIV self-testing and self-sampling could therefore be the key to helping people, especially from high-prevalence groups, to diagnose HIV infections earlier and contributing to the fight against further transmission of HIV.

In many countries legal, ethical, financial and other barriers still prevent the common use of this new tool. While more and more low-income countries with high HIV prevalence rates have been supporting self-testing opportunities, many high- and middle-income countries have not yet authorized or legalized the sale, distribution and use of HIV self-tests. The current status of policies in regard to self-testing in countries of the WHO / EURO region is shown in Table 15.

Table 15: Policies for self-testing in countries of the WHO / EURO region

Authorized for use, sale & distribution		
Belgium	Italy	Netherlands
Czech Republic	Latvia	United Kingdom
Denmark	Malta	France
Monaco		
Authorized only for use		
Belarus	Moldova	Ukraine
Luxemburg	Spain	
Policy under development		
Albania	Ireland	Lithuania
Armenia	Kosovo	Sweden
Bulgaria	Kyrgyzstan	Switzerland
Germany		
Explicitly illegal		
Portugal		

Source: HIV self-testing research and policy hub; (HIVST, 2017b)

The **United Kingdom** was one of the first European countries to legalize the sale of self-test kits in April 2014. In addition two programmes providing free HIV self-sampling kits online for use at home were piloted in 2013 and 2014. The success of these programmes led to the establishment of a national self-sampling service co-commissioned by Public Health England and 89 local authorities (AVERT, 2017a). A study of the national HIV self-testing service in the UK demonstrated its feasibility and acceptability. 91% of the 602 participants in the survey felt encouraged to get tested by the service, 98% would use the service again and 91% were satisfied with the additional support being offered (Cary, 2017).

Encouraging the use of HIV self-tests is one of the new approaches highlighted in the **French National Sexual Health Strategy 2017-2030 Agenda**. Since 2015 HIV self-tests can legally be purchased in France without prescription but costs are not covered by the health insurance so far. Several NGOs have been supporting the official introduction of the HIV self-test in France with a number of initiatives to inform target groups and the general public (e.g. phone platform, public communication campaigns, information / training for pharmacists, fact sheets for pharmacists) (SIDA, 2017).

In a pilot project in the **Netherlands** HIV self-tests have been made available for purchase through the Internet. During the 2015 HIV testing week an online campaign motivating MSM and migrants was launched, attracting more than 34.000 visitors to the campaign's website (www.time2test.nl). During the campaign phase an oral fluid-based test (OraSure) could be ordered for free together with a manual, online instructions and counselling services. Preliminary results of the study linked to the campaign showed that target groups were reached (HIVST, 2016).

Other European countries are currently discussing their policies regarding HIV self-testing and self-sampling. In **Sweden**, for example, test-kits are available on the Internet, imported from other European countries, but their use is neither officially permitted, nor is it recommended by the Public Health Agency of Sweden (Folkhälsomyndigheten, 2015b). The situation in Germany is very similar. The Federal Ministry of Health, recognizing the promising results in other countries such as the UK, France and Australia, has been considering the national accreditation of HIV rapid tests for use at home (DÄ, 2017). In **Switzerland** the Federal Commission for Sexual Health does not recommend home sampling or self-testing (AHS/BAG, 2014; EKSG, 2013) but a policy allowing these approaches is currently being discussed. **Portugal**, which still prohibits HIV self-testing by law, has also been discussing these issues and a home sampling pilot project has been carried out.

Other countries

The **Australian** Government has approved HIV self-testing as an additional, complementary testing option in 2014. The effect of availability of HIV self-testing on HIV testing frequency in gay and bisexual men at high risk of infection was studied in a waiting list randomised controlled trial (FORTH). The trial showed that HIV self-testing doubled the frequency of testing in this risk group, and there was a nearly four times increase in non-recent testers compared with standard care (and without reducing the frequency of facility-based HIV testing) (Jamil et al., 2017). A cross-sectional online survey, conducted in Beijing, **China**, in 2016, including users of a popular Chinese gay networking application with an unknown or negative HIV status, showed that the uptake of HIV self-testing among MSM was high (nearly 40%) and that more than 90% were interested in using a self-testing kit in the future (REN et al., 2017).

Unitaid is funding the HIV Self-Testing Africa (STAR) Initiative, a 5-year project to catalyse the market for HIV self-testing. Between 2015 and 2017 the world's largest evaluation of HIV self-testing to date was conducted, generating information about the effective distribution of self-tests, as well as on the feasibility, acceptability and impact of this approach. 4.8 million HIV self-test kits will be distributed across **Malawi, Zambia, Zimbabwe, South Africa, Lesotho and Swaziland** by 2020. (LSHTM, 2017)

HIV self-testing research and policy hub

HIVST.org is an online platform created by a group of experts in the field (e.g. from WHO, academia and other sectors). This collaborative effort aims to generate and share information and resources with the global public health community, civil society groups, health policy makers, and programme managers. Besides presenting up-to-date information on HIV self-testing issues, an evidence map and a policy map as well as a range of tools are being offered (HIVST, 2017b).

Evidence

Examining the effects of HIV self-testing compared to standard HIV testing services: a systematic review and meta-analysis, including five randomized controlled trials with 4145 participants from four countries, showed a twofold increase of testing frequency in most trials without any indication of harm attributable to HIVST or potential increases in risk-taking behaviour. The review authors have recommended the use of HIVST but also encourage further research on related issues, such as linkage to confirmatory testing, prevention, treatment and care services (Johnson et al., 2017).

A systematic literature review on **experiences using and organizing HIV self-testing** in different countries showed that HIV self-testing increased capacity to reach priority populations and expanded opportunities for service delivery. Self-testing was preferred to facility-based testing due to increased convenience and confidentiality, especially within stigmatized populations. In addition it **empowered people by providing greater control over individual testing needs**. The authors of the review suggested that HIV self-testing should be offered as an additional testing option and be incorporated into national policies (Qin et al., 2018).

Growing evidence from various countries and among many population groups has shown that **HIV self-testing is highly acceptable, often reaching people who may not otherwise test** (e.g. men, adolescents, key populations). Research results also show that HIV self-testing can be performed accurately. Risk behaviours, social harm or adverse events in response to a reactive (positive) test result have not been observed. Following HIV self-testing good linkage to treatment, care and prevention services

can be achieved, especially when this is supported by and integrated into community-based systems (WHO, 2017c).

WHO published updated guidelines on HIV self-testing and partner-notification in 2016, providing guidance on how these services can be integrated into community-based and facility-based approaches and how they can be adapted to specific population groups (WHO, 2016b). Together with Unitaid WHO has also published reports on the market and technology landscape for HIV rapid diagnostic tests for HIV self-testing, providing a summary of the current testing gap and emphasizing the potential roll of HIV self-testing in reaching the UNAIDS 90-90-90 targets (UNITAID, 2017).

News

An innovative **HIV self-testing app (HIVSmart!)**, which has been tested successfully in Canada and South Africa, is being introduced to all 60 **UNAIDS Fast-Track Cities**, aiming to bridge the divide between testing, treatment and care. The multilingual app works with any approved HIV self-test assessing the users' HIV exposure risk, interpreting their self-test results and linking those who test positive to treatment. In addition it is designed to help people stay on treatment by providing a confidential way for patients and treatment providers to communicate (AVERT, 2017b).

HIV self-testing could soon be possible using a biochip attached to a smartphone as demonstrated in a proof-of-concept study by the University College London, UK. This application, using a drop of blood from a finger prick, could give patients a result within 10 seconds and enable an immediate linkage to counselling, confirmatory testing, treatment and related services (Turbé et al., 2017).

Recommendations

WHO strongly recommends offering HIV self-testing as an additional approach to HIV testing services as HIV self-testing is believed to be “**an empowering and innovative way to reach first-time testers, undiagnosed people living with HIV or those at ongoing risk requiring frequent testing**” (WHO, 2016d).

The directors of **WHO's Regional Office for Europe and ECDC** have **been urging their Member States to improve testing practices** by emphasizing the need for efficient HIV counselling and testing services, including rapid diagnostic services, community-based HIV testing and HIV self-testing opportunities, to reduce the number of future HIV infections in Europe (ECDC, 2017a).

3.5 HIV TESTING SERVICES FOR MIGRANTS

Migrants, especially from high-prevalence countries, belong to the key target groups of most national HIV/AIDS policies. HIV testing services often need to be adapted due to cultural differences and language barriers, but it is essential that no individual should undergo compulsory or mandatory testing for HIV or other STIs.

The term migrant is defined as “**any person who lives temporarily or permanently in a country where he or she was not born and has acquired some significant social ties to this country**” (Council of Europe). Migrant populations living in the EU suffer a disproportionate burden of HIV, delayed diagnosis and poorer access to antiretroviral treatment. Challenges and cultural barriers often hinder access to HIV testing and counselling opportunities and adequate linkage to treatment and care.

In 2016 approximately 45% of all newly diagnosed patients in **Switzerland** were of Swiss nationality, 24% were from other European countries and 9% from countries with a high HIV prevalence. It is assumed that the majority of the HIV positive migrants were infected before their arrival in the country (BAG, 2017d). Projects have been developed using specially trained, **cultural-sensitive mediators and social-media activities** to reach migrant groups more effectively and to increase testing rates in these groups (SRK, 2017).

In **Sweden** almost 80% of all people reported with an HIV-infection in 2016 were foreign-born with many of these infections occurring in Thailand, Eritrea and Spain (Folkhälsomyndigheten, 2017b). According to the “Health and Medical Care for Asylum Seekers and Others Act” county councils should offer **a health examination to all migrants within two months of arriving** in Sweden. In addition to a health interview, laboratory tests including voluntary screening for HIV and other examinations have been recommended. The proportion of migrants and asylum seekers taking this health examination has varied considerably between counties (SWE-GOV, 2012).

In **France** 23% of new HIV infections are attributable to **female, heterosexual migrants**, who often face problems linked with sexual and reproductive health. Therefore a number of targeted prevention efforts have been introduced as part of an overall prevention and healthcare approach. These include screening and vaccination programmes, the creation of primary care centers offering family planning and other healthcare services. In addition “**health appointments**” have been systematically offered to newly arrived migrants systematically within four months of their arrival in France (FRA, 2017).

In Bavaria, one of **Germany's** largest federal states, a large number of migrants, especially those arriving from high prevalence areas have been routinely tested for HIV immediately after arrival without an adequate follow-up. According to the national **German Asylum Act**, decisions concerning the choice of tests to be used are the responsibility of the individual federal states concerned. In this case the Bavarian health authorities have decided against the WHO, ECDC and RKI recommendations of a **cultural-sensitive approach, offering voluntary counselling and testing** for asylum seekers, refugees and other migrants (RKI, 2016)

In **Portugal** the National Programme to Prevent and Control HIV infection, AIDS and Tuberculosis supported a study on **Immigrants: HIV and other sexually transmitted infections** by the Institute of Hygiene and Tropical Medicine with the participation of three non-governmental organizations (GAT, AJPAS and Ser+). Key findings have pointed to the importance of continuing to invest in initiatives that promote the reduction of risk behaviours and HIV testing of immigrants as a key-population group (DGS, 2015).

Other common challenges are **late diagnosis and delayed linkage to treatment and care**. A study in the **Netherlands**, including all HIV positive patients between January 1996 and June 2014, showed that 53% of patients, especially heterosexual men, those older than 50 years and **immigrants from HIV endemic areas**, first presented themselves at a late stage of their infection (de Coul et al., 2016).

While in most Western European countries migrants are defined as target groups in HIV prevention and testing policies, the **United Kingdom** specifically choose black Africans, especially when living in high-prevalence communities. In 2015 the proportion of people diagnosed with HIV who were born in the **UK** (52%) exceeded the proportion born abroad (48%) for the first time since the 1990s (PHE, 2016a). Public Health England has re-emphasized the need for better implementation of the **annual testing recommendation** for high risk groups, mainly MSM and **black African men and women** (PHE, 2017d).

Evidence

Supported by the ECDC an online-survey about **national recommendations regarding HIV testing and counselling for migrants and ethnic minorities in 31 EU/EEA/EFTA Member States** was conducted together with a review of national recommendations, guidelines and other relevant policy documents. 22 out of 29 responding countries identified migrants and four countries identified ethnic minorities as being particularly vulnerable to HIV. 16 countries explicitly recommended offering an HIV test to migrants/ethnic minorities. While HIV testing was not mandatory in any country, some countries clearly facilitated this practice. The authors of this study concluded that **many countries recognized benefits of HIV testing in migrants and ethnic minorities**, at both individual and community levels, but not all countries identified the need to test these groups for HIV (Alvarez-del Arco et al., 2013).

A cross-sectional study of HIV positive migrants has been conducted in 57 HIV clinics in nine European countries. This covered 2009 participants, who had been living on average eight years in their host countries, **63% acquired the HIV infection post migration** (72% among MSM, 58% and 51% in heterosexual men and women, respectively). 71% of migrants from Latin America and the Caribbean and **45% of those originating from sub-Saharan Africa were infected post migration** (Alvarez-Del Arco et al., 2017).

As part of the **EURO HIV-EDAT** project and supported by the EC, a study on the “**access to HIV testing and linkage to care for migrant populations in Europe**” has been conducted in 7 European countries (**Belgium, Denmark, France, Germany, Portugal, Slovenia and Spain**).

Key findings:

- Legal definitions and representations vary greatly from one country to the other.
- Sub-Saharan Africans represent the most-at-risk migrant population for HIV in Europe, followed by Latin Americans and the Caribbeans.
- Significant diversity exists within the EU Member States regarding policy and legal frameworks for access to healthcare and HIV services.
- Free and anonymous testing is available in all participating countries.
- Some countries provide only for emergency services for irregular migrants (with some exceptions); but ART is often not provided).
- In other countries irregular migrants are permitted access to health care including ART on equal grounds as nationals however administrative barriers may be problematic.
- The proportion of late diagnosis or undiagnosed HIV among migrants is disproportionately high, indicating a lack of access to HIV prevention and testing services.
- Many social and cultural factors prevent migrants from using relevant healthcare services, e.g. low perceived risk, lack of knowledge on where to get tested and distrust in the medical system.

(EDAT, 2017a)

Guide to best practices to improve early testing and care among migrant populations in Europe

Based on the findings from research studies conducted under the Euro HIV EDAT project, practical guidelines aimed at improving HIV testing and linkage to care for migrant populations in Europe have been developed (AIDES, 2017).

Key elements of these guidelines are:

- Reaching migrant populations by developing a relevant communication strategy (including e.g. social / cultural mediators) and implementing innovative intervention strategies
- Offering adapted HIV services to promote HIV testing and care tailored to the specific needs of migrant populations (by e.g. ensuring a culturally adapted client provider relationship)
- Promoting community-based VCT programmes and outreach activities with HIV rapid testing alongside pre- and post-test counselling, favouring community-based staff or doctors trained to understand the social norms of the community
- Strengthening linkage to care and improving retention in care of migrant populations, especially by promoting cooperation between statutory healthcare services and community-based VCTs as well as by involving migrant populations in the care process.

Recommendations

WHO, UNHCR and UNAIDS oppose all forms of compulsory or mandatory HIV testing on human rights and public health grounds. In a **Policy Statement on HIV Testing and Counselling for Refugees and other persons of concern to UNHCR** the three organizations examined the role of HIV testing and counselling in health facilities in increasing access to HIV prevention, treatment, care and support services for refugees, asylum-seekers, internally displaced persons and stateless persons. Specific recommendations for further actions based on WHO's HIV testing and counselling guidelines were included (UNHCR/WHO/UNAIDS, 2014).

National HIV testing services policies and programmes should **ensure to eliminate all non-voluntary forms of testing**. No individual, even as a member of a high-risk group or arriving as migrant or refugee from a high-prevalence country, should undergo compulsory or mandatory testing for HIV or other STIs (WHO, 2017c).

ECDC has published a special report on HIV and migrants in 2017 highlighting the following priority options for action (ECDC, 2017b):

1. Strengthen prevention and testing programmes for migrants

- Develop more effective awareness-raising and prevention interventions for migrant populations most affected by HIV - including migrants from countries with generalised HIV epidemics, migrant MSM and migrants who inject drugs - and targeted prevention programmes for migrants at risk of post-arrival acquisition of HIV.
- Promote earlier and increased uptake of HIV testing among those migrants who are most at risk, by expanding community-based testing and adopting other innovative and targeted approaches to increase access to testing for migrants.
- Reduce missed opportunities for HIV testing and diagnosis in health services, particularly in primary care, through routine or opt-out testing where appropriate and implementation of indicator condition-guided testing.
- Develop more focused and effective case detection approaches for the hardest-to-reach undiagnosed individuals among migrant populations.

2. Address barriers to provision and update of services for migrants

- Consider revising laws and policies that prevent migrants, in particular undocumented migrants, from accessing HIV prevention and testing services.
- Ensure that ART is made available free of charge to undocumented migrants.
- Develop and implement more effective approaches to eliminate stigma and discrimination towards migrants in healthcare settings and to reduce HIV-related stigma and discrimination within migrant populations.

3. Strengthen the evidence base on HIV and migrants

- Improve monitoring of post-arrival HIV acquisition among migrants.
- Collect EU country-specific data to identify sub-groups of migrants who are most at risk.
- Improve data on HIV testing and late diagnosis among migrants and sub-groups of migrants who may be at increased risk of HIV.
- Collect data on risk behaviour and risk reduction among sub groups of migrants most at risk of HIV infection.

3.6 FINDING THE RIGHT WINDOW PERIOD

The time following an event with a possible exposure to HIV and a reliable and definite result of an HIV test is a time of great uncertainty for the individual and of great risk to others. Scientists and policy makers need to ensure that recommendations for the selection of a window period are based on the highest level of up-to-date evidence.

The window period is the time between HIV infection and the detection of HIV-specific antigen and antibodies using serological assays (= seroconversion period). The length of this period depends on an individual's immune response and the type of serological assay used. Testing during this time can result in false negative results. A definite HIV diagnosis can only be made after the window period, which has been shortened by the introduction of more sensitive assays.

Most European countries now use 4th generation ELISA tests (anti-HIV-1 & anti-HIV-2 antibodies, p24 antigen) and rapid point-of-care tests (HIV-1- and HIV-2-antibodies). Scientific and technological advances have led to more reliable test with shorter window periods (Figure 20).

France

According to the French National Authority for Health a negative result of a 4th generation ELISA test only indicates that the person hasn't been infected with HIV if no risk of infection has been taken within a 6 week period prior to the test. A negative result of a rapid test or self-test can't be relied on, if a risk has been taken within a 3 month period prior to the test (HAS, 2015).

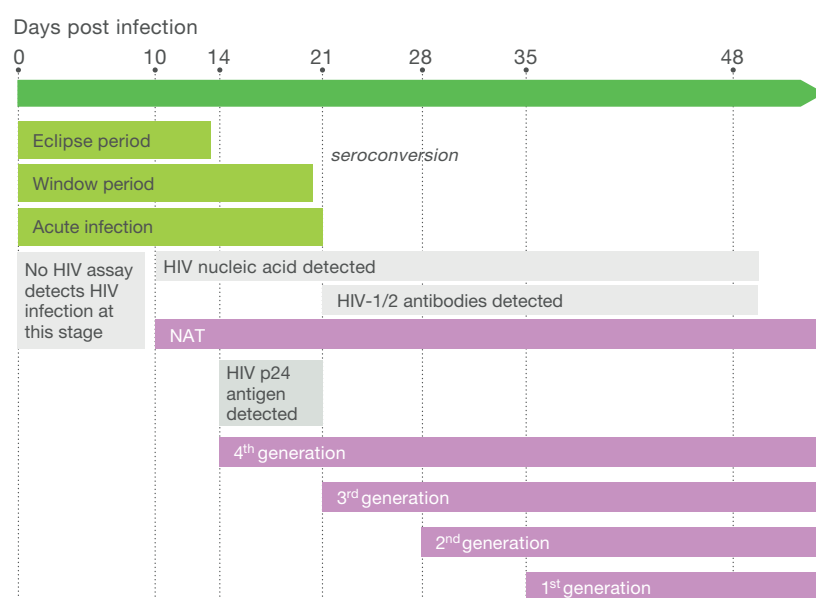
Germany

Following the 2015 revision of the HIV guidelines the window period has been reduced to 6 weeks provided that a 4th generation test has been used and the person tested has not been exposed to HIV within this period. The window period for rapid tests remains at 12 weeks with no further HIV transmission risk taken during this period, even if these tests are also able to detect the p24-antigen (Rabenau et al., 2015).

Netherlands

The Dutch GP society recommends using a 4th generation ELISA test 3 months after taking a potential risk or earlier, if indicated by a physician. In this case and if the result is negative, another test should be taken at 3 months following the risk-taking event. If a rapid test is used a 4th generation ELISA test is required to confirm a positive result. If a rapid test is negative, it should be repeated 3 months after the last risk-taking event (NHG, 2013).

Figure 20: Detecting HIV-infection with various formats and generations of in vitro diagnostics over the natural history of infection



Source: Adapted from WHO, Consolidated guidelines on HIV testing services, 2015

Test	Attributes of the serological assays	Place	Required qualification
NAT (1992)	HIV nucleic acid	Facility-based	Laboratory technician
4th (1997)	IgG and IgM antibodies and HIV p24 antigen	Facility-based	Laboratory technician
RDT 4th	Rapid diagnostic test (Results in 20-30 min)	Facility-based	Health-care worker, trained lay provider
		Non-Fb	Community worker, trained lay provider, self-test
3rd (1991)	IgG and IgM antibodies	Facility-based	Laboratory technician
2nd (1987)	IgG antibodies only, higher specificity and sensitivity	Facility-based	Laboratory technician
1st (1985)	IgG antibodies only	Facility-based	Laboratory technician

Portugal

According to the 2014 update of the HIV laboratory guidelines the window period is four weeks, if a 4th generation test has been used and the person tested has not been exposed to HIV within this period. In certain cases renewed testing following a first negative test has been recommended as early as four weeks following the possible exposure (e.g. occupational or non-occupational exposure) or risk taking event (e.g. if the partner is HIV positive, for sex workers, IDUs, MSM, after sexual abuse / rape). The window period for rapid tests is 12 weeks with no further HIV transmission risk taken during this period (DGS, 2014).

Sweden

A comprehensive review and analysis by the Public Health Agency of Sweden and the Reference Group for Antiviral Therapy has led to new recommendations for follow-up times after exposure to HIV (Gaines et al., 2016). A 6-week window period after a suspected HIV exposure or after termination of PEP / PrEP prophylaxis is recommended when a laboratory-based combination 4th generation test is used. When a rapid response test is used an 8-week window period after a suspected HIV exposure or after termination of PEP / PrEP prophylaxis is recommended. If an HIV-2 exposition is suspected, a 12-week window period is recommended for both 4th generation laboratory tests and rapid response tests (Folkhälsomyndigheten, 2015c).

Switzerland

The Swiss Federal Office of Public Health has recommended the use of a combined rapid point-of-care test 10-14 days after a risk-taking event if the patient does not have any clinical symptoms indicating a possible HIV

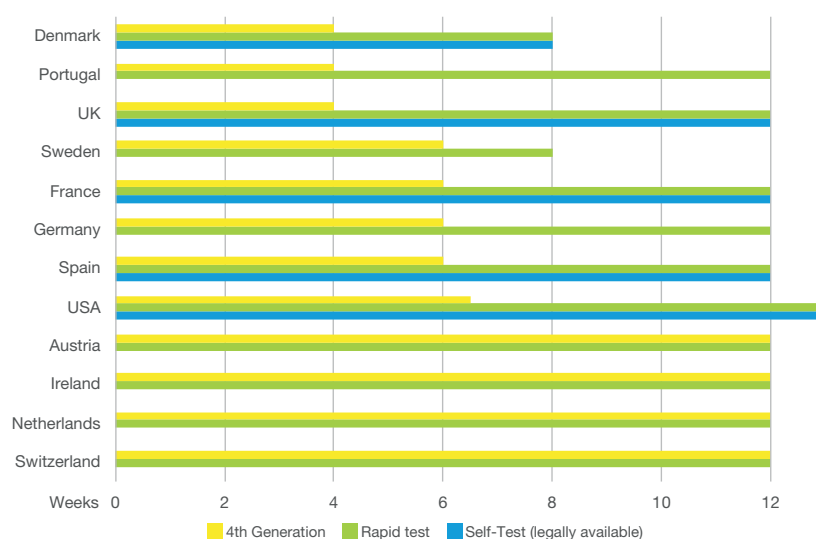
infection requiring an immediate test. If the first screening test is negative, a second combined test should be conducted two weeks after the initial one. If the second one is also negative, a third combined test should be administered three months after the risk-taking event to definitely exclude an HIV infection (FOPH, 2013). The Federal Commission for Sexual Health has been discussing reducing this 3-month window period following the example of most other European countries.

UK

Based on the 2008 UK guidelines for HIV testing the use of the latest 4th generation test on a venous blood sample performed in a laboratory is recommended. This test should be offered 4 weeks after a specific exposure. If a patient already attends a testing site before this date, the test should be offered directly in order to be able to identify an acute HIV infection. This test should then be repeated 4 weeks after a specific exposure. A negative result of a 4th generation test performed at 4 weeks post-exposure is highly likely to exclude an HIV infection and a further test at 8 weeks post-exposure is only recommended if there has been a high risk of infection during the reported event. Patients with an ongoing risk of an HIV infection should be advised to retest at regular intervals (BASHH, 2014). The window period for rapid HIV blood tests only recommended for community outreach projects and drop-in clinics, can be highly variable. PHE suggest that most HIV infections should be detected within 6 weeks of exposure to HIV (PHE, 2017c).

The window periods communicated in national HIV testing guidelines of countries included in this study as well as from other countries with a concentrated HIV epidemic are shown in Figure 21.

Figure 21: Window periods for 4th generation ELISA tests, rapid tests and self-tests in selected countries



Source: Country chapters and national sources:

*Sweden: If a HIV-2 exposition is suspected, a 12-week window period is recommended for both 4th generation laboratory tests and rapid response tests (Folkhälsomyndigheten, 2015c).

*USA: CDC 45 days (4th Gen.) / 90 days (all other tests), (CDC, 2017b)

*Austria: Aidshilfe Österreich, Jahresbericht 2016, (AHÖ, 2016)

*Portugal: Diagnóstico e Rastreio Laboratorial da Infecção pelo Vírus da Imunodeficiência Humana (VIH) (DGS, 2014)

*Spain: Guía de recomendaciones para el diagnóstico precoz del VIH en el ámbito sanitario, (ESP, 2014); HIV self-tests have been legalized in 2017.

*Ireland: Health Service Executive, HIV and AIDS, (HSE, 2017)

*Denmark: Statens Serum Institut, HIV, (SSI, 2017)

Recommendations

According to **WHO** individuals who test HIV-negative should receive brief health information about their test results and a recommendation on retesting based on the individual's level of recent exposure and/or ongoing risk of exposure. In WHO's 2015 Consolidated guidelines on HIV testing services the organization emphasized "...retesting is needed only for HIV-negative individuals who report recent or ongoing risk of exposure. For most people who test HIV-negative, additional retesting to rule out being in the window period is not necessary and may waste resources." Retesting after four to six weeks is recommended for those individuals who report a specific, suspected exposure to HIV in the previous three months (WHO, 2015a).

The 2014 **European Guideline on HIV testing** suggested that individuals who test negative on the initial HIV screening should be considered uninfected unless the patient presents with symptoms of a primary HIV infection or has a history of recent high-risk exposure (less than 6 weeks for 4th generation assays, less than 12 weeks for other assays). Following a recent exposure the tests should be repeated at 6 weeks and 12 weeks respectively from the time of this exposure (Gökengin et al., 2014).

The **US CDC** has published research findings estimating the window period for all 20 FDA-approved HIV tests (using plasma) (Delaney et al., 2016). CDC recommends laboratory testing using antigen/antibody tests on blood plasma less than 45 days after a possible HIV exposure and, if the result is negative, follow-up testing 45 days after the possible HIV exposure. For all other tests, CDC recommends testing again at least 90 days after a possible HIV exposure to ensure that a negative test result is accurate (CDC, 2017b).

3.7 SUPPORTING PARTNER NOTIFICATION

Voluntary assisted partner notification has shown to be highly acceptable, leading to high HIV detection rates among partners, giving them the opportunity to be linked to HIV prevention, treatment, care and support services. WHO recommends implementing this approach as a routine part of HIV testing services and it should be offered not only to newly diagnosed persons, but also periodically to all HIV positive persons as part of their treatment and care.

Partner notification is – in most countries – a voluntary process where health professionals or trained lay providers support individuals diagnosed with HIV or other communicable diseases to inform their sexual or drug injecting partners and to offer these partners counselling and testing services. A range of assisted or passive approaches has been used, e.g. contact or provider referral, telephone helplines and online tools such as web applications.

While the potential benefits for the individual and for public health are indisputable, legislative frameworks, recommendations and services conducted by specially trained professionals are lacking in many countries.

France, Germany, Switzerland and Portugal have neither legislative frameworks on partner notification nor any specialized professionals trained in this field. However advice on this topic has been routinely offered during post-test counselling services in the different testing sites in all of these countries.

- In **France** research studies have now been initiated to assess the feasibility and acceptability of partner notification interventions (HAS, 2017a).
- In **Portugal**, two NGOs, GAT and CheckpointLX, have developed the **CheckMe application for mobile phones**, including information on HIV and STIs, maps with counselling and testing centers as well as an option for anonymous notification of partners (GAT, 2017b).
- In **Switzerland** the “**normalisation of voluntary partner information**” was an innovative aspect included in the national HIV strategy (FOPH, 2011).

Under the **Swedish** “Communicable Diseases Act” infections with HIV, syphilis, chlamydia, gonorrhoea, hepatitis B and C are notifiable. Therefore it is **compulsory** for healthcare providers to initiate partner notification, for index patients to accept partner notification and for partners to undergo testing and, if indicated, treatment. Partner notification services vary between counties. In some counties patients are referred to STI centres with specialist contact tracing staff (non-HIV infections) or to infectious diseases clinics at university hospitals (HIV infections). In other counties healthcare providers making an HIV or STI diagnosis also initiate partner notification together with the patient. This is the most common approach in Sweden. However in some cases, when index patients or their partner(s) do not follow the partner notification instructions, they can be referred to the county medical officers, who can contact the individual by letter, phone or, if necessary, a home visit (ECDC, 2013).

In the **Netherlands** partner notification is considered to be essential to be able to test and treat the individuals concerned preventing the further spread of STI or HIV infection. It has been estimated that about one third of all STIs in the Netherlands were detected following the notification of a partner either by the infected person or a specially trained STI nurse at the healthcare centre where the infection was diagnosed. **RIVM has examined the existing partner notification mechanisms in Dutch STI centers.** Tracing the partners of MSM continues to be very difficult because of frequent anonymity and multiplicity of these partners. While only 46% of partners of MSM with an STI could be traced, 87% of partners of heterosexual women and 63% of partners of heterosexual men have been found and notified. A further problem is the limited time available to STI nurses for counselling and discussions on

partner notification. **Special courses for STI nurses have been offered** (RIVM, 2015).

The municipal healthcare services, STI clinics, SOA AIDS Netherlands and the College of General Practitioners have developed a **special online tool** (<https://partnerwaarschuwing.nl>) to improve partner notification services in the Netherlands. A wide range of information is offered together with a web-based opportunity of notifying partners via Email or SMS including important information. This can also be done anonymously (PW, 2017).

In the **United Kingdom** partner notification has been **shown to be effective in diagnosing HIV** and clinical services managing patients with HIV or STIs are expected to initiate partner notification as part of HIV management. National guidelines on partner notification for adults were published in 2015, defining relevant outcomes and proposing standards. Processes and best clinical practice examples have been described in the BASHH **Statement on Partner Notification for STIs and the SSHA Manual for Sexual Health Advisers** (NAT, 2015).

In 2017 Public Health England observed the highest positivity rates of all HIV testing activities (3.9%) in individuals tested following a notification by their partners (PHE, 2017d).

WHO conducted a systematic review and meta-analysis on the **effectiveness of assisted partner notification services in improving HIV test uptake and diagnosis**, and the occurrence of harmful or adverse events in 2016. Four randomized controlled trials and six observational studies including more than 5000 index patients from eight countries were included. Results showed that offering assisted partner notification services led to a **1.5-fold increase in the uptake of HIV testing services** among partners compared to passive referral. In addition the **proportion of HIV-positive partners was 1.5 times** higher with assisted partner notification than with passive referral, indicating the need for increased efforts in the area of partner identification. Few instances of violence or harm were observed. WHO therefore strongly recommends voluntary assisted HIV partner notification services to be offered as part of a comprehensive package of testing and care for newly diagnosed persons, and periodically to all HIV positive persons (Dalal, 2017).

Recommendations

As part of its 2015 consolidated guidelines on HIV testing services, **WHO** has published a special supplement with guidelines on HIV self-testing and **partner notification** (WHO, 2016):

Key recommendations

- HIV partner notification services should always be **voluntary** requiring **the consent of the HIV-positive client**, who should always be counselled about the benefits and risks enabling the client to make a safe and informed choice.
- **Criminal justice, law enforcement or other non-health-related service providers should not be involved** in any form in the partner notification process.
- Assisted partner notification services **increase the uptake of HIV testing** among partners of HIV-positive clients, and **high proportions of HIV-positive people are diagnosed** and linked to care and treatment.
- **Report of social harm or other adverse events following voluntary HIV partner notification have been rare.** Training for providers and associated counselling and support services should be offered. Clients should also have the right to decline.
- **Supportive policies are essential for effective and safe HIV partner notification programmes.** Legal barriers as well as all practices that might stigmatize, criminalize or discriminate against people from key population groups and people with HIV should be removed.

3.7 SUPPORTING PARTNER NOTIFICATION

ECDC has published a technical report on **Public health benefits of partner notification for sexually transmitted infections and HIV** in 2013. The report shows a wide range of partner notification practices in Europe determined by diverse legal and policy frameworks and influenced by cultural and social factors (ECDC, 2013).

ECDC recommended, for example, to

- **Strengthen the evidence-base** with respect to the positive and negative effects of laws making aspects of partner notification compulsory and of laws on criminalisation of transmission.
- Address gaps in the evidence and **determine the most effective approaches** to partner notification in Europe, which can be adapted to different country contexts, population groups and healthcare settings, including primary care settings.
- **Improve awareness with respect to the importance of partner notification** in STI prevention and control among policy-makers and the need for partner notification interventions to be adequately resourced.

Voluntary assisted partner notification services should be offered as part of a comprehensive package of testing and care offered to people with HIV.

3.8 REVIEWING THE COST-EFFECTIVENESS OF HIV TESTING

A combination of facility- and community-based approaches, including self-testing and self-sampling opportunities, needs to be selected to reach all people living with HIV who are unaware of their infection. Cost effectiveness is critical when considering HIV testing and screening methods and more research is urgently needed in this field.

Cost-effectiveness studies in the field of HIV testing and screening are rare. Process and outcome indicators vary between countries, regions and service providers. Cost analysis, representative studies, health economics modelling analysis, mathematical simulation models and prospective cohort studies have been used to calculate or estimate the costs per patient, the average cost per diagnosis and the cost-effectiveness of a number of approaches.

Policy makers are increasingly using cost-effectiveness studies and mathematical modelling projects to be able to choose, develop and implement the right approaches for HIV testing services for a specific area, tailored to the epidemiological context and the respective at risk population. The fragmented and de-centralised structure and organization of national health and health insurance systems in some countries (e.g. in Germany, Netherlands, Sweden) make it difficult or almost impossible to conduct representative cost-effectiveness studies in the area of HIV testing and counselling. Other countries, e.g. France or the United Kingdom, who have a centralised national health system, have included cost-effectiveness studies into the evaluation process of their national HIV testing strategies.

In 2017 a **comprehensive economic modelling process** was conducted in **France** to identify the most cost-effective approach for HIV testing in the general population and in the high-risk target groups. **Testing frequencies and related costs** were analysed (in Euros / QALY; Table 16). Cost-effectiveness seemed to be achieved by a testing frequency of three months in MSM, and of one year for IDUs and migrants from high-prevalence countries. **General population HIV screening offered once in a lifetime or even every 10 years also appears to be cost-effective** (HAS, 2017b).

Table 16: Summary of cost-effectiveness results (€ / Quality adjusted life years (QALY)) of different HIV screening strategies: general population and key populations in France (HAS, 2017)
(Not viable = a more efficient and cost-effective alternative is already available)

Test frequency	General population	MSM	IDU	Migrants (from high-prevalence areas)
Once in a life	37.268	Not viable	Not viable	Not viable
Every 10 years	50.293	16.000	Not viable	24.667
Every 5 years	Not viable	19.940	20.152	Not viable
Every 3 years	121.647	Not viable	24.456	28.126
Annual	338.914	20.250	33.026	58.709
Every 6 months	Not viable	31.200	90.247	217.506
Every 3 months	1.254.199	40.340	190.857	234.467

In the **UK** a **cost-effectiveness analysis using a dynamic compartmental model** showed that providing annual HIV testing to MSM, injecting drug users and people from HIV-endemic countries, and one-time testing for all other adults, would prevent 4–15% of infections, requiring one-fourth as many tests to diagnose each PLHIV, at a cost of £ 17.500 / QALY gained. The authors concluded that **annual HIV testing of key populations in the UK is very cost-effective** and that **additional one-time testing of all other adults could identify the majority of undiagnosed PLHIV** (Long et al., 2014).

The **number of people needed to be tested** in the **UK** to **identify one HIV diagnosis** varies considerably between different settings (PHE, 2017d):

- **228** people in **extremely high prevalence areas**
- **181** people in **community settings**
- **139** people through the **self sampling service**

A study including 86000 people in a socioeconomically deprived area in London with an HIV prevalence rate of 8 / 1.000 adults showed that **offering HIV testing with a rapid test in primary care to all newly registered patients led to a four-fold higher HIV diagnosis rate**. The data from this research trial has also been used for a **health economics modelling analysis**, including all the costs associated with HIV testing and treatment. Results showed that over a 40 year-period, primary care-based HIV screening in high prevalence areas would cost an estimated £ 26.626 per Quality Adjusted Life Year (QALY) gained and would therefore be cost-effective and life saving. The study authors recommended offering screening to all people living in high HIV prevalence areas (> 2 HIV infections / 1000 adults) in England (Baggaley et al., 2017).

Using data collected through the BerDa system by all 20 VCT testing centers in **Switzerland** over a 5-year period, a **cost-effectiveness analysis** was conducted and both the **number needed to test (NNT)** as well as the **positive predictive value (PPV)** were calculated. Checkpoints were the most cost-effective and showed the highest PPV (92%). Estimated costs per HIV diagnosis were CHF 3.600 at Checkpoints, while in other settings like clinics and testing centers the costs were more than five times higher (Schmidt, 2013).

Table 17: Number needed to test and positive predictive value of HIV tests in Swiss VCT-sites (2008-2012)

Test site category	Check-points	AIDS-Hilfen	Clinics	ProFa	Total
N tested	11 082	5 860	23 717	4 065	44 724
N false positive	14	14	60	1	89
N confirmed	155	18	60	1	234
% false positive	0.1%	0.2%	0.3%	0.02%	0.2%
% confirmed	1.4%	0.3%	0.3%	0.02%	0.5%
positive					
NNT	71	326	395	4065	191
PPV	92%	56%	50%	50%	72%
CHF per diagnosis	3 600	16 300	19 800	203 250	9 600

Source: Schmidt et al., BAG, Deutsch-Österreichischer AIDS-Kongress 2013, (Schmidt, 2013)

In Portugal a cost-analysis was made from the community perspective, comparing data from Lisbon with other European cities. The cost of HIV VCT services for one patient and per reactive test in a community-based setting were:

Costs	Lisbon	Athens	Paris
VCT for one patient	€ 75	€ 40	€ 100
Per reactive test	€ 2200	€ 2000	€ 6200

The authors of the study concluded that **community-based services detected a high number of HIV cases at a relatively low cost** in many European countries and therefore should be recommended for early detection of HIV and fast linkage to care (Perelman et al., 2017).

As part of the **OptTest** project a study using a mathematical simulation model has been conducted to determine the survival benefits, **cost and cost-effectiveness of different HIV testing strategies** in different settings, regions and priority groups in Europe. A focused analysis was done for **France, Spain and Estonia** and findings will now be extrapolated to other European countries to generate country- and region-specific guidance {OptTEST, 2017 #302}. The authors of this study suggested using a tailored approach responding to each country's HIV epidemic, recommending that

- MSM should be tested every 3 to 12 months in France and Estonia, and every 6 to 36 months in Spain.
- PWID should be tested every 3 to 12 months in Spain and every 12 to 36 months in France. In Estonia, PWID should be tested at least monthly, if not more frequently.
- Current HIV testing in the general population should be maintained in France and Spain, and increased in Estonia with an additional test every three years.

The **US** Centers for Disease Control and Prevention recommended **non-targeted opt-out HIV screening** in healthcare settings. A **prospective cohort study** nested in a larger quasi-experiment comparing this non-targeted approach with a physician-directed diagnostic rapid HIV testing approach in an urban emergency department was conducted as part of the Denver ED HIV Opt-Out Trial. The aim was to evaluate the cost-effectiveness of both approaches. During a 16-month period the two approaches were alternated in 4-month time blocks. Compared to physician-directed diagnostic

testing, non-targeted HIV screening was more costly but identified 11 more HIV infections at an incremental cost of US\$ 10.693 per additional infection. The authors of this study concluded that more effective and less costly HIV testing strategies would be required for an ED setting (Haukoos, 2014).

	Non-targeted	Physician-directed
Eligible patients	28.043	29.925
HIV tests	6.933 (25%)	243 (0.8%)
New HIV infections diagnosed	15 (0.2%)	4 (1.7%)
Average cost per diagnosis	\$9.932	\$7.839

A study was carried out comparing the cost-effectiveness of HIV testing strategies in **Washington D.C., USA** (HIV prevalence 2.4% in 2015), including testing data from 3 types of testing sites (clinics, hospitals, and community-based organizations). The findings showed that while routine testing identified more newly diagnosed infections and prevented more infections than targeted testing, **targeted testing was more cost-effective per diagnosis and per transmission prevented overall**. In addition both testing approaches were most cost-effective in preventing new transmissions when conducted by community-based organizations (\$25,037 routine; \$33,123 targeted) (Castel, 2015).

As part of the development process for the 2015 consolidated guidelines for HIV testing services, **WHO** conducted a **systematic review of HIV testing costs in high and low income countries**. The aim of this review was also to gather information on the types of HIV testing services provided and their associated costs for different approaches across diverse settings, populations and contexts. The review covered only those studies reporting at least the proportion of people who were diagnosed as HIV-positive, the cost per person tested, and the information about how these costs were calculated. These studies were identified by an extensive database and web search for the period between January 2001 and May 2015. While a number of studies from low- to upper-middle income countries (China, India, Viet Nam and countries of sub-Saharan Africa) matched the inclusion criteria only a limited number of studies from high-income countries (Denmark and USA) could be included. A summary of the costs per person tested and per HIV positive case detected in high-income countries is listed in Table 18b.

Table 18a: Categories of reported costing data:

1	Personnel costs	e.g. cost of staff or volunteer, including salaries, stipends, per diem, cell phones, and benefits
2	Facility & Infrastructure costs	e.g. building and facility operating costs, maintenance and rents
3	Vehicles & Other transport	e.g. purchase and operation of mobile vans for outreach testing, vehicles or other transport for staff including mileage
4	Equipment & Durables	e.g. CD4 machine, Printers, Refrigerator
5	Test kits & Consumables	e.g. rapid test kits, gloves, cotton swabs, lancets, reagents
6	Training for staff and volunteers	
7	Promotion materials	e.g. brochures, handouts, advertising campaigns
8	Administrative costs	e.g. overheads, office supplies, record keeping, data management and analysis support, logistics, planning, supervision, quality assurance, laboratory fees)
9	Referral & Assessment	e.g. referral cards, transport voucher, point-of-care CD4
10	Facilitated linkage ending in enrolment	e.g. active case management, patient navigator, home-based ART initiation
11	Other specialty costs	e.g. pay for performance incentives

Source: Annex 5. Systematic review of HIV testing costs in high and low income settings (Johnson, 2015)

Table 18b: Summary of the costs per person tested and per HIV positive case detected in high-income countries

	General population	Key population	Other at-risk populations
Costs per person tested			
Mobile		Median: \$231 Range: \$96–\$709 (4 studies)	Median: \$999 Range: \$520–\$1,529 (1 study)
Facility	Median: \$56 Range: \$20–\$115 (4 studies)	Median: \$177 Range: \$93–\$209 (3 studies)	Median: \$109 Range: \$90–\$129 (2 studies)
Other		Median: \$67 Range: \$34–\$160 (1 study)	Median: \$803 Range: \$52–\$1,642 (2 studies)
Total	Median: \$56 Range: \$20–\$115 (4 studies)	Median: \$123 Range: \$34–\$709 (6 studies)	Median: \$803 Range: \$52–\$1,642 (5 studies)

	General population	Key population	Other at-risk populations
Costs per HIV positive case detected			
Mobile		Median: \$11.101 \$4,059 to \$19.703 (4 studies)	Median: \$15.749 \$12.694 to \$18.022 (1 study)
Facility	Median: \$4.581 \$2.171 to \$31.830 (4 studies)	Median: \$13.744 \$4.219 to \$17.005 (3 studies)	Median: \$8.417 \$6,276 to \$10.558 (2 studies)
Other		Median: \$6.526 \$2.843 to \$29.334 (1 study)	Median: \$8.136 \$6,098 to \$25.026 (2 studies)
Total	Median: \$4.581 \$2.171 to \$31.830 (4 studies)	Median: \$9.505 \$2.843 to \$29.334 (6 studies)	Median: \$12.694 \$6,098 to \$25.026 (5 studies)

4. CONCLUSION

Scaling up access to HIV testing and adapting services offered to the respective epidemiological context is critical to ending the AIDS epidemic by 2030. This study has described the complexity of the challenges posed and the diversity of stakeholders involved as well as the variety of measures and initiatives taken by HIV testing services. It has also illustrated the need for coordinated approaches, adapted to the national health structures and local circumstances.

Globally HIV testing has been increasing in the past decade and services have been expanded, including the implementation of several new approaches such as community-based testing, rapid diagnostic tests and self-testing opportunities. Data collection for monitoring and evaluation purposes in order to improve testing strategies, policies and guidelines still remains challenging. The ability to respond adequately to the respective situations and the changing HIV epidemiology has been weakened by the lack of systematically collected testing data. In recent years many of the new HIV infections in European countries have been diagnosed in older men and in some countries also in heterosexual women in migrant populations. This has led to a need for both targeted testing interventions for specific populations as well as an increasing awareness of the situation among healthcare workers.

In most countries a variety of voluntary HIV counselling and testing opportunities have been offered. Facility-based HIV testing remains essential but community-based testing services need to be expanded to meet national and global targets and to reach key population groups.

Provider initiated testing and counselling also remains vital for the response to the HIV epidemic as it helps to normalize the HIV testing process, leading to higher testing coverage and earlier diagnosis. More physicians, especially general practitioners, need to be trained to recognize HIV risk factors and indicator conditions so that they are able to offer appropriate counselling and testing to individual patients.

HIV self-testing and self-sampling are promising innovative approaches to encourage people who want to know their status but prefer a confidential test. These approaches should be made available in addition to other facility- or community-based HIV testing services.

Sexually transmitted diseases and other HIV co-infections continue to be of critical importance in the response to the HIV epidemic. Multi-Disease testing can increase detection rates, allowing earlier linkage to treatment and care and reducing the risk of further transmission.

Migrants, especially from high-prevalence countries, belong to the key target groups of most national HIV/AIDS policies. HIV testing services need to be adapted taking cultural differences and language barriers into account whilst ensuring that no individual has to undergo compulsory or mandatory testing for HIV or other STIs.

The time following an event with a possible exposure to HIV and a reliable and definite result of an HIV test is a time of considerable uncertainty for the individual and possibly of great risk to others. Scientists and policy makers need to ensure that recommendations for the selection of a window period are based on the highest level of up-to-date evidence.

Voluntary assisted partner notification has proved to be highly acceptable, leading to high HIV detection rates among partners, giving them the opportunity to be linked to HIV prevention, treatment, care and support services. WHO recommends implementing this approach as a routine part of HIV testing services and it should be offered periodically to all HIV positive persons as part of their treatment and care as well as to newly diagnosed persons.

A combination of facility- and community-based approaches, including self-testing and self-sampling opportunities is needed to reach all people living with HIV who are unaware of their infection. Cost effectiveness is also critical when considering HIV testing and screening methods and more research is urgently needed in this field.

This study has attempted to describe the multifold challenges being faced in the field of HIV counselling and testing, the situation with regard to the stakeholders involved as well as the differing measures and initiatives presently being taken. It has also clearly illustrated that a coordinated approach is needed for the development and implementation of national HIV testing strategies specifically designed to respond to the individual contexts at national, regional and local levels. This is particularly necessary

as transmission patterns, characteristics of key population groups, national health systems and other aspects vary greatly by country and epidemiological area. Countries need to identify those evidence-based solutions suitable to their respective societal and cultural contexts. The exchange of knowledge, experiences and good practices, both nationally and internationally, would certainly be most useful in the development and implementation of policies and programmes. Securing political commitment, raising public awareness as well as including innovative solutions (e.g. by using social media) are all essential to reach those who remain unaware of their HIV infection.

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