

The epidemic of HIV infection and AIDS, promotion of testing, and innovative strategies

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Summary. In Europe, the incidence of new diagnoses of HIV infection in 2008 was 86.7 cases per one million population, and most cases were attributable to sexual transmission. In Italy, in 2007, the incidence was 60.0 cases per one million population (in the areas in which surveillance exists), and 73.7% of the cases were attributable to sexual transmission. At present, there are an estimated 170 000-180 000 persons living with HIV/AIDS in Italy, some of whom are unaware of being infected. Based on available epidemiological data and taking into consideration the level of risk of exposure to HIV, we describe several proposals for promoting access to HIV testing in diverse population groups and contexts, including some innovative approaches. The promotion of HIV testing is fundamental for public health and human rights and must be associated with treatment, care and prevention activities, which must be guaranteed for the entire population.

Key words: HIV, acquired immunodeficiency syndrome, epidemiology, HIV seroprevalence, infection transmission.

Riassunto (*Epidemia dell'infezione da HIV/AIDS, promozione del test HIV e strategie innovative*). In Europa, il tasso delle nuove diagnosi di infezione da HIV nel 2008 è stato pari a 86,7 casi per milione di abitanti; la maggiore proporzione di casi è attribuibile alla trasmissione sessuale. In Italia nel 2007, l'incidenza (nelle aree in cui è attivo il sistema di sorveglianza) è stata pari a 60,0 casi per milione di residenti e i casi attribuibili alla trasmissione sessuale sono il 73,7%. La stima attuale delle persone viventi con HIV/AIDS in Italia è pari a 170 000-180 000 casi, di cui una parte non sa di essere infetta. Sulla base dei dati epidemiologici disponibili e in relazione alle diverse probabilità di trasmissione, vengono presentate alcune proposte per promuovere l'accesso al test HIV in diversi gruppi di popolazione e in diversi contesti, anche attraverso l'utilizzo di approcci innovativi. La promozione del test HIV è un imperativo per la sanità pubblica e per i diritti umani, che si deve associare ad attività di cura, assistenza e prevenzione, garantite per tutta la popolazione.

Parole chiave: HIV, sindrome da immunodeficienza acquisita, epidemiologia, seroprevalenza di HIV, trasmissione dell'infezione.

INTRODUCTION

In the fight against HIV infection, many governments are attempting to improve prevention and have proposed some important changes at both the public-health and social level. Countries in Europe and Central Asia, through the "Dublin Declaration on Partnership to Fight HIV/AIDS in Europe and Central Asia" of 2004, have established some principles and objectives for guaranteeing access to healthcare and HIV testing for the entire population, especially those with the greatest risk of exposure to infection. At the global level, the World Summit of 2005 and the United Nations General Assembly High-Level Meeting on HIV/AIDS of 2006 intended to guarantee the progressive improvement of the prevention, treatment, and care of HIV infection, with the promotion of universal access to testing beginning in 2010.

EPIDEMIOLOGY OF HIV INFECTION AND AIDS IN EUROPE

Infectious diseases constitute one of the three leading causes of death worldwide, together with cardiovascular disease and neoplasms. Of the deaths due to infectious diseases, a high percentage is due to HIV infection/AIDS, especially in economically developing countries [1]. In 2008, the World Health Organization (WHO) estimated that there were approximately 33.4 million (31.1-35.8 million) persons living with HIV infection, of whom the majority live in Sub-Saharan Africa [2].

WHO, Joint United Nations Programme on HIV/AIDS (UNAIDS) and the European Commission have recommended that all European countries implement national surveillance systems for HIV infection, so as to provide updated information on the spread of infection in Europe. The data on HIV/

AIDS collected by the diverse surveillance systems of individual European countries are sent annually to the European Centre for Disease Prevention and Control (ECDC), which coordinates and centralises data handling and analysis [3].

New diagnoses of HIV infection in Europe

In Europe, 528 058 new diagnoses of HIV infection were reported in the period from 2000 to 2008. In 2008, 48 of the 53 countries that make up the WHO European Region (data not available for Austria, Denmark, Liechtenstein, Monaco, Russia and Turkey) reported 51 600 new diagnoses of HIV infection, with an incidence of 86.7 per one million population. Of these diagnoses, 13.0% were among persons between the ages of 15 and 24 years, and 35.0% were among females. The largest percentage of cases (42.0%; $n = 21\,912$) were attributed to heterosexual transmission, though if excluding diagnoses among persons from countries with a generalised epidemic, the percentage decreases to 37.0%. Approximately one fifth of the reported diagnoses (19.0%; $n = 8920$) were among men who have sex with men (MSM), and around one fourth (27.0%; $n = 12\,597$) were among injecting drug users (IDU). Finally, 653 cases (1%) were due to vertical transmission and 129 cases to other causes (*i.e.*, nosocomial infection, transfusion or use of blood products).

The 10 countries with the highest incidence in 2008 were, in decreasing order: Estonia, the Ukraine, Moldova, Latvia, Kazakhstan, England, Uzbekistan, Portugal, Switzerland, Kyrgyzstan and Belgium. According to ECDC, the three European macro areas (Western Europe, Central Europe, and Eastern Europe) differ in terms of both the incidence of infection and the modes of transmission. In 2008, the incidence was highest in Eastern Europe (179.4 per one million population; $n = 25\,542$), followed by Western Europe (72.4 per one million population; $n = 24\,296$) and Central Europe (15.0 per one million population; $n = 1762$). Most cases in Eastern Europe are attributable to syringe exchange, whereas those in Western Europe are mainly due to heterosexual or homosexual contact, and those in Central Europe to homosexual contact. The incidence of new cases of HIV infection has nearly doubled, from 44.0 cases per one million population in 2000 to 89.0 cases per one million population in 2008, in the 43 countries that consistently provided data from HIV surveillance in this period [3].

AIDS cases in Europe

In the WHO European Region, 342 768 cases of AIDS were reported in the period from 2000 to 2008, with 7565 cases in 2008 (incidence of 8.6 cases per one million population). In 2008, most cases were reported in Western Europe (11.6 per one million population; $n = 4724$), followed by Eastern Europe (8.1 per one million population;

$n = 2311$) and Central Europe (2.8 per one million population; $n = 530$). Nonetheless, the incidence of new diagnoses of HIV infection was higher in Eastern Europe, compared to the other two areas.

Between 2000 and 2008, following the introduction of highly active antiretroviral therapy (HAART), the number of reported AIDS cases in the European Region drastically decreased, from 12 072 cases (incidence of 19.0 per one million population) to 7564 cases (incidence of 12.0 per one million population); actually, in Eastern Europe, in the same period, the number of reported cases increased, from 835 (incidence of 6.6 per one million population) in 2000 to 2311 (incidence of 18.2 per one million population) in 2008.

In 2008, the most commonly reported AIDS-indicator diseases among adults and adolescents were *Pneumocystis carinii* pneumonia (16.4%), tuberculosis (15.4%) and Wasting Syndrome (10.2%). As of the end of 2008, there were 185 139 deaths due to AIDS, of which 2800 occurred in 2008 [3].

SURVEILLANCE OF AIDS AND HIV INFECTION IN ITALY

In Italy, AIDS has been subject to mandatory reporting since 1986 (Ministerial Decree of November 28, 1986) [4]. Reports from the entire country are collected and analysed at the Centro Operativo AIDS (National AIDS Unit, COA) of the Istituto Superiore di Sanità. In Italy, on March 31, 2008, the Ministry of Labour, Health, and Social Policy issued a decree for implementing a surveillance system for new diagnoses of HIV infection [5]. With this decree, HIV infection was included among the diseases that are subject to mandatory reporting, which had already included AIDS [6]. The data on new diagnoses of HIV infection are collected and analysed by COA; thus COA is responsible for both AIDS surveillance and the surveillance of new diagnoses of HIV infection and publishes national data on HIV infection and AIDS.

In Italy, health decisions are made at the Regional level. At present, not all of the country's 21 Regions have a surveillance system for new diagnoses of HIV infection, and there are currently 11 Regional/Provincial systems. In 1985, systems were created in the Regions of Lazio and Friuli-Venezia Giulia and in the Provinces of Modena, Trento and Bolzano; in 1988, a system was created in the Veneto Region; in 1997, a system was created in the Province of Sassari; in 1999 in the Piemonte Region; in 2001 in the Liguria Region; in 2002 in the Province of Rimini; and in 2007 in the Province of Catania and in the Puglia Region [7]. Given that the population of these areas represents only one third of the national population, the data cannot be considered as representative of

Italy's epidemiological situation, though they can provide indications on nationwide trends in infection [8].

EPIDEMIOLOGY OF HIV INFECTION AND AIDS IN ITALY

New diagnoses of HIV infection in Italy

From 1985 to 2007, a total of 40 676 new diagnoses of HIV infection were reported in Italy (28 760 males and 11 902 females; data missing for 14 persons). The incidence of new diagnoses peaked in 1987; it then decreased and since 1998 has been stable. In 2007, there were 1679 new diagnoses, with an incidence of 6.0 per 100 000 population. The highest incidence was observed in the Province of Rimini, whereas the lowest incidence was in the Puglia Region.

The median age at the time of diagnosis has increased over the years, from 26 years for males and 24 years for females in 1985 to 37 and 33 years, respectively, in 2007. The mode of transmission has also changed: the proportion of infections represented by IDUs has decreased (from 69.0% in 1985 to 8.6% in 2007), whereas the proportion represented by cases attributable to sexual contact has increased (from 13.3% in 1985 to 73.7% in 2007) (*Figure 1*).

The proportion of new diagnoses of HIV infection represented by foreigners increased from 11.0% in 1992 to 32.0% in 2007. Most of the infected foreigners are from Africa (41.2%) and Latin America (25.2%), whereas 16.0% are from other European countries. The main mode of transmission among foreigners is heterosexual contact (54.1%) [8].

AIDS cases in Italy

From 1982 to December 31, 2008, there were 60 346 AIDS cases reported in Italy. Of these, 75.7% were males, 1.3% of paediatric age (<13 years) and 7.8% foreigners. The median age at diagnosis (calculated for adults) was 35 years for males and 32 years for females: as found for cases of HIV infection, the age at diagnosis of AIDS has increased over time.

The Regions with the highest number of reported cases in 2008 were, in decreasing order: Lombardia, Liguria, Emilia-Romagna and Toscana, showing a North-South gradient in the spread of AIDS in Italy. As found for HIV infection, the proportion of cases represented by foreigners has increased, from 5.1% in 1995-1996 to 22.1% in 2007-2008.

IDUs, which include homosexual IDUs, represent the greatest proportion of cases (56.1%). As found for HIV infection, the proportion of cases attributable to heterosexual contact (homosexual and heterosexual) has increased, with a consequent decrease in the cases due to other modes of transmission. Nearly half (42.5%) of the females with AIDS acquired infection through sexual contact with a partner who was aware of being seropositive, compared to 12.2% of males.

Only 34.0% of the cases reported since 1996 had undergone antiretroviral treatment before being diagnosed with AIDS. Of note is the finding that the percentage of persons having undergone treatment differs with the mode of transmission: 23.0% of the persons infected through sexual contact, compared to 50.0% of the IDUs. The pathologies at clinical onset have also varied according to whether or not treatment had been provided: of the persons who had undergone antiretroviral therapy, compared to

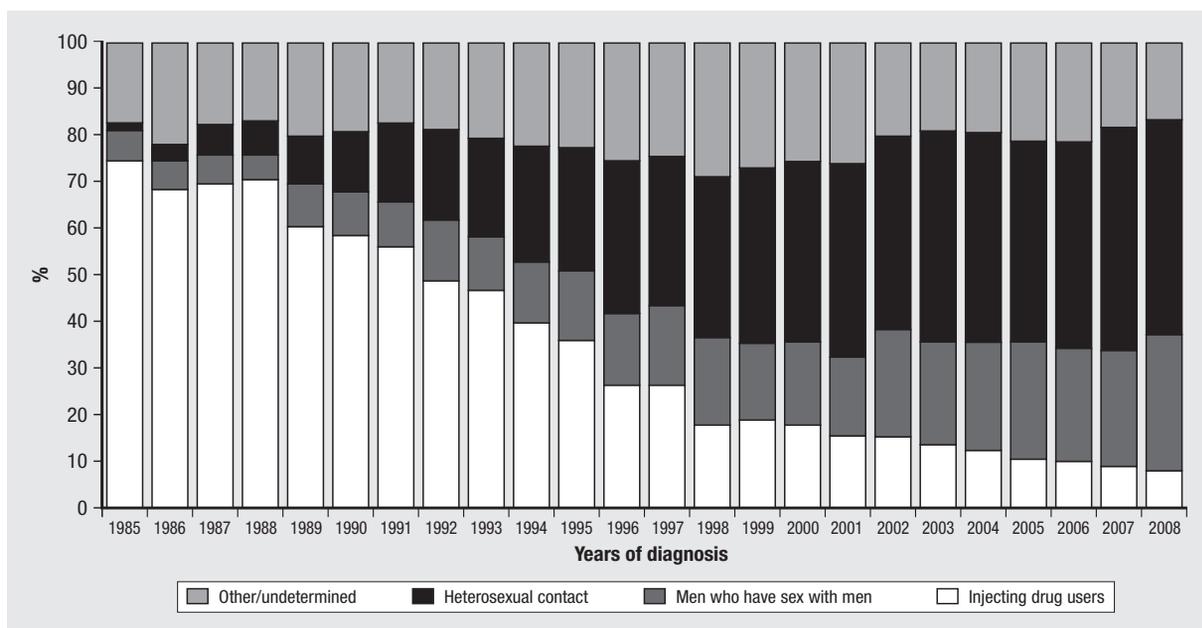


Fig. 1 | Percent distribution of new diagnoses of HIV infection, by mode of transmission and year, Italy [8].

those who had not, the proportion of persons with *Pneumocystis carinii* pneumonia or toxoplasmosis were lower, whereas the proportion of persons with pulmonary or esophageal candidiasis, lymphomas or cervical carcinomas were greater for persons who had undergone treatment.

The proportion of persons who became aware of being seropositive only upon being diagnosed with AIDS has increased progressively; in 2008 they represented 60% of the reported AIDS cases; the proportion was higher among persons who had acquired infection sexually and among foreigners [8].

PREVALENCE AND EXPOSURE CATEGORIES

In Italy, an estimated 170 000-180 000 persons are currently living with HIV/AIDS, a proportion of whom are unaware of being infected. According to data from the national surveillance systems for HIV infection and AIDS, the characteristics of the persons who recently acquired infection differ from those who acquired infection 10 years ago [8], in particular:

- most infections are no longer diagnosed among IDUs but instead among older adults who become infected through sexual contact;
- the proportion of new diagnoses represented by foreigners has increased;
- more than half of the persons with AIDS became aware of being seropositive only upon being diagnosed with AIDS (diagnostic delay).

At present, according to the classification of UNAIDS/WHO, Italy has a concentrated HIV epidemic, that is, with a prevalence lower than 1% among pregnant women, greater than 5% in at least one population subgroup, and with more than one subpopulation at risk of infection [9]. In fact, various prevalence studies carried out in Italy have shown that the prevalence is low among pregnant women and higher among certain population groups (Table 1) [10-18].

Table 1 | Prevalence of HIV infection, by population group, Italy [10-18]

Population group	HIV prevalence	Reference study
Injecting drug users	14.6%	[10]
Men who have sex with men	11.6%	[11]
Persons with a current sexually transmitted infection	9.4%	[12]
Prison inmates	7.5%	[13]
Foreigners with a current sexually transmitted infection	5.5%	[12]
Foreign sex workers	1.6%-2.5%	[14-16]
Non-injecting drug users	1.6%	[10]
Pregnant women	0.1%	[17]
Occasional blood donors	0.0236%	[18]
Repeat blood donors	0.0027%	[18]

Table 2 | Infectivity estimates for HIV sexual transmission according to various cofactors [20-23]

Mode of transmission	Infectivity (transmission per 1000 exposures)
Heterosexual intercourse with uncircumcised HIV-negative individual	13.2
Receptive anal intercourse	8.2
Heterosexual intercourse with genital ulcer disease in the HIV-negative individual	7.5
Heterosexual intercourse with circumcised HIV-negative individual	5.1
Early-stage HIV infection in index case	3.2
Late-stage HIV infection in index case	2.6
Insertive vaginal intercourse during menstrual period	1.9
Heterosexual intercourse without genital ulcer disease in the HIV-negative individual	1.5
Receptive vaginal intercourse	0.8
Mid-stage HIV infection in index case	0.7
Insertive anal intercourse	0.6
Insertive vaginal intercourse	0.4
Receptive oral intercourse	0.4

These prevalence rates greatly depend on the diverse modes and probabilities of transmission. HIV is transmitted in three ways: i) sexually (contact with genital secretions and contact of anal-genital mucus membranes); ii) parenterally (use of infected syringes, accidental exposure to infected blood, transfusion of infected blood or blood components); and vertically (in the intra-uterine phase, during birth, and through breast feeding). The probability of acquiring infection through a single contact varies with the mode of transmission (Table 2): parenteral transmission has the highest probability [19], whereas certain types of sexual contact constitute a greater risk than others [20-23].

Based on the available epidemiological data and on the diverse probabilities of transmission, we analysed the advantages and disadvantages of promoting HIV testing in different population groups (Table 3), taking into consideration the different contexts, the possible use of innovative approaches for promoting testing, and the frequency of testing for specific risks, as reported in studies conducted in Italy and other countries [8, 13, 24-35].

INNOVATIVE APPROACHES TO HIV TESTING

In studies conducted in Italy and in other countries, innovative approaches, such as the use of rapid HIV tests, the opt-out strategy, and tests for recent infections, have been proposed. Rapid tests represent a new tool whose use is becoming increasingly widespread. These tests could be particularly

Table 3 | *Advantages and disadvantages of promoting HIV testing in different population groups in Italy [8, 13, 24-35]*

Population group	Advantages	Disadvantages	Rapid HIV tests	Frequency of testing
Injecting drug users (IDUs)	Population numerically limited (approximately 100 000 persons) Identifiable and well defined High prevalence of HIV infection High HIV transmission rate	Difficult to reach if not referring to public drug-dependency centres (SerT)	Useful for reaching persons who do not present at SerTs and for epidemiological surveys conducted on the street	Every 6-12 months
Men who have sex with men (MSM)	High frequency of at-risk behaviour High HIV transmission rate Individuals very collaborative	Population numerically large (approximately 500 000 15-49 year-olds) Not always easily identifiable Difficult to contact and reach	Useful for reaching persons who do not present at clinical centres and for epidemiological surveys conducted on the street and in gathering places	
Persons with a sexually transmitted infection (STI)	High prevalence of HIV infection High HIV transmission rate Easy to identify and contact (at STI centres)	Persons with asymptomatic or undiagnosed infection are difficult to reach		
Foreigners	Subgroups with high prevalence (MSM, persons from endemic areas, sex workers, IDUs, prison inmates, persons with STIs) Easy to identify	Population numerically large (approximately 4 300 000 persons) Difficulties with communication and cultural barriers Not always easy to reach Low access to health facilities	Useful in temporary detention centres	
Prison inmates	Population numerically limited (approximately 65 000 person) Easy to identify and contact High prevalence of HIV infection High proportion of foreigners, IDUs, sex workers, MSM	Political and logistical impediments Lack of interest in own serostatus		
Sex workers	Population numerically limited (approximately 50 000 persons) High prevalence in some subgroups (foreigners, IDUs, persons with STIs) Numerous at-risk sexual contacts	Difficult to identify Difficult to contact	Useful for reaching persons who do not present at clinical centres and for epidemiological surveys conducted on the street	
Persons with HIV-related signs/symptoms	Population numerically limited High prevalence of HIV infection Easy to reach because they present at clinical centres	Signs and symptoms at times not recognised as HIV-related by healthcare workers		
Heterosexuals and the general population	Population with the greatest potential expansion of the epidemic Possible to propose testing on a larger scale, by involving general practitioners	Numerically huge population Low perception of risk of infection Difficult to reach and identify Difficult to determine who is at risk Low prevalence of HIV infection and thus a greater potential for false-positive test results False sense of security for those who test negative		
Pregnant women	Easy to identify and reach Prevention of perinatal transmission Individuals very collaborative	Low prevalence of HIV infection		First test before or at the beginning of pregnancy Second test in the third trimester for women at greater risk of infection

useful for at-risk persons who rarely take advantage of healthcare services and for epidemiological surveys conducted on the street or in public gathering places. If targeting populations with a high prevalence of HIV infection and with limited numbers of people, the use of rapid tests could greatly contribute to prevention, especially for persons who are unlikely to present at healthcare facilities. However, the wide-scale use of these tests among the general population or indiscriminately among heterosexuals could lead to a high number of false-positive results, given the low prevalence of HIV infection in these groups, and thus end up being counter-productive or even dangerous [36-38].

The opt-out approach is currently recommended by the US Centres for Disease Control and Prevention (CDC) for persons with signs and symptoms of HIV infection and for pregnant women. With the opt-out approach, the individual, following an interview, is subjected to HIV testing, without the need to obtain informed consent, and testing is performed unless the individually expressly refuses [35, 39]. In Italy, the opt-in approach has been preferred, that is, the individual who agrees to undergo testing, following a pre-test interview, must sign an informed consent form before testing is performed [40]. The opt-out approach seems to be particularly indicated in those cases in which diagnosing the infection would be extremely beneficial to both the individual, who could then receive proper treatment, and the community, in that the high probability of transmission could be reduced (persons with sexually transmitted infections (STI), pregnant women, and IDUs). For all of the innovative approaches mentioned above, healthcare workers must be properly trained, so that they are capable of providing accurate information and appropriate counselling.

Serological tests for recent infections have been used in recent years in various countries, and they allow recent infections (seroconversion ≤ 6 months) to be distinguished from past infections (seroconversion > 6 months) [38, 41-44]. These tests are useful for epidemiological purposes (to estimate the true incidence of infection), prevention (to identify those groups at greatest risk and perform contact tracing), public health (to plan the targeted allocation of resources), clinical purposes (early antiviral treatment), and vaccination (for targeted vaccination campaigns for the population groups most at risk).

THE SUITABILITY OF PROMOTING HIV TESTING

The international guidelines of WHO and UNAIDS recommend that all countries, both those with a generalised epidemic and those with a concentrated epidemic, prepare recommendations for developing strategies for HIV testing [39]. The suitability and success of campaigns for promoting testing in specific contexts and populations mainly depend on the potential benefit of knowing whether an individual

is seropositive and of informing that individual of his/her seropositivity. In fact, the promotion and improvement of access to testing can have a number of advantages, providing that the following conditions are met:

- persons whose test result is negative must have access to prevention services which provide information on avoiding exposure;
- persons whose test result is positive must have access to appropriate treatment and care;
- persons whose test result is positive must be informed of how to avoid transmitting the virus to others and be protected from discrimination.

Nonetheless, WHO discourages the wide-scale use (*i.e.*, for the general public) of testing in countries with a concentrated epidemic, such as Italy, given that most of the population has a low prevalence of infection and this approach would probably be unfeasible and of little use, and thus inappropriate [36]. In any case, the access to and offering of testing must be improved, taking into consideration the specific population group, the available health facilities, and the users' needs. Failing to propose testing to persons at-risk is considered to be substandard medical practice [36]. Depending on the risk factors and on an evaluation made by health personnel, the test could be proposed in cases deemed to be appropriate, with a varying degree of insistence: in a proactive manner (for persons at high risk), strongly recommended, or just recommended.

DIVERSE STRATEGIES FOR PROMOTING HIV TESTING IN DIFFERENT POPULATION GROUPS

Based on the above considerations, on the type of HIV epidemic in Italy, and on the guidelines of WHO and UNAIDS [36, 39], we propose the following strategies for promoting HIV testing in certain population groups (*Table 3*).

- *IDUs*: testing for all persons at public drug-dependency centres (known as "SerT"); the use of rapid tests as part of epidemiological investigations conducted on the street, to reach persons who do not refer to SerTs; repeating the test at least once a year for IDUs [25]; use of the opt-out approach;
- *MSM*: testing for all persons who report at-risk contact; the use of rapid tests as part of epidemiological investigations conducted on the street or in gathering places frequented by MSM; repeating the test after each exposure to risk [45];
- *persons with STIs*: testing for persons with a current STI; repeating the test after each exposure to risk [45]; use of opt-out;
- *foreigners*: testing for all persons who report at-risk behaviour, especially those from highly endemic countries; use of rapid tests in detention centres; repeating the test after each exposure to risk [45];
- *prison inmates*: testing upon incarceration; re-

peating the test after each exposure to risk [45]; consider using opt-out, depending on the incidence and prevalence in the specific prison and geographic area;

- *sex workers*: the use of rapid tests as part of epidemiological investigations conducted on the street; repeating the test after each exposure to risk [45];
- *persons with signs/symptoms related to HIV infection*: testing of all persons with signs and/or symptoms suggestive of HIV-related pathologies (e.g., tuberculosis); evaluation of the use of opt-out, depending on the specific signs and symptoms;
- *heterosexuals and the general public*: testing for all persons who report at-risk contact and who present signs and/or symptoms suggestive of HIV infection; proposing testing with the collaboration of general practitioners; repeating the test after each exposure to risk [45];
- *pregnant women*: testing for all pregnant women; testing at the beginning of the pregnancy and repeated in the third trimester for women with a greater risk of exposure; use of opt-out.

CONCLUSIONS

The promotion of HIV testing is imperative for public health and human rights; it must be associated with treatment, care, and prevention, which must be guaranteed and accessible for the entire population [39]. When proposing testing, the characteristics of the population group and the needs of these individuals must be taken into consideration. Depending on the population group, testing strategies could include: opt-out, active offering of the test, innovative approaches for reaching certain at-risk groups, and the use of rapid tests.

The recommendations for promoting testing for Italy's population and for the most vulnerable

population groups touch upon some fundamental points:

1. epidemiological monitoring of HIV infection must be performed;
2. there is an urgent need to improve prevention and information on HIV infection and testing;
3. testing should be recommended as part of routine practice at STI clinical centres, SerTs, infectious-disease clinics, and antenatal clinics;
4. testing should be proposed to all persons with signs and/or symptoms of infection, all persons with a current STI, persons who have engaged in at-risk sexual behaviour, and persons who have injected drugs in their lifetime;
5. all pregnant women should undergo HIV testing;
6. it is important to identify infection in those persons who are unaware of their seropositivity [36];
7. additional financial and human resources must be made available for implementing effective programs for proposing HIV testing.

According to the declaration of Dublin of 2004, HIV prevention is a primary objective of the European Community. Prevention is mainly achieved by improving access to HIV testing and treatment, fighting stigmatisation and discrimination, improving and harmonising the systems for infection surveillance, and monitoring the epidemic and at-risk behaviours [46].

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