

Aspects of the Italian legislation related to HIV testing

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Summary. Italy has adhered to international declarations regarding the prevention, care, and treatment of HIV/AIDS and has adopted the fundamental interventions for surveillance and control; access to testing is defined by Law 135 of 5 June 1990. At the time, the Ministry of Health issued decrees to define national epidemiological surveillance systems for new HIV infections. The decree provides indications on the data to be collected, data flow, the modes of data transmission respecting security measures and some recommendations regarding access to HIV testing. It is thus necessary to develop national recommendations on appropriate methods for considering the diverse phases of access to testing in relation to the level of awareness of the minor, the outcome and divulging of the test.

Key words: HIV serodiagnosis, informed consent, minors.

Riassunto (*Alcuni aspetti della normativa italiana correlati all'accesso al test HIV*). L'Italia ha aderito alle dichiarazioni internazionali in materia di prevenzione, cura e trattamento dell'HIV/AIDS e ha adottato gli interventi fondamentali per la sorveglianza e il controllo; l'accesso ai test è definito dalla legge 135 del 5 giugno 1990. Il Ministero della Salute ha diramato il decreto per la sorveglianza epidemiologica delle nuove infezioni da HIV. Il decreto fornisce indicazioni sui dati da raccogliere, il flusso di dati, le modalità di trasmissione dei dati nel rispetto delle misure di sicurezza e alcune raccomandazioni riguardo l'accesso al test HIV. È necessario sviluppare raccomandazioni nazionali riguardo ai metodi adeguati per poter valutare le diverse fasi di accesso al test in relazione al livello di consapevolezza del minore, l'esito e la divulgazione dello stesso.

Parole chiave: test HIV, consenso informato, minori.

INTRODUCTION

In Italy, according to data from the surveillance of HIV infection and the monitoring of AIDS cases, provided by the Istituto Superiore di Sanità, in recent years only 34.0% of reported cases have been adequately treated with highly active antiretroviral therapy (HAART). This means that for more than 62.9% of previously untreated persons with AIDS, the development of HIV-related pathologies, both major and minor, could have been delayed or avoided. The effectiveness of therapy depends on early diagnosis. In fact, epidemiological data clearly indicate that there is a close correlation between the prevalence of HIV testing and the prevalence of use of HAART, and there is an evident need to develop strategies for promoting the wider use of testing [1, 2].

Italy has adhered to international declarations regarding the prevention, care, and treatment of HIV/AIDS and has adopted the fundamental interventions for surveillance and control. With regard to prevention, European authorities have defined the

key points of action in the fight against AIDS, as well as recommendations for conducting targeted information campaigns, including the specific targets to be reached. In particular, these indications have been provided in the following documents:

1. "the Declaration of Dublin" (February 2004) – written during the 2004 European Presidency;
2. "Communication from the Commission to the Council and the European Parliament on Combating HIV/AIDS with the European Union and in the neighbouring countries, 2006-2009" – document based on the principles and priorities established in the working paper of the Commission (December 2005);
3. "the Bremen Declaration on Responsibility and Partnership – Together Against HIV/AIDS" (13 March 2007) – document produced at the Ministerial Conference and signed by the Ministers and Government representatives who are responsible for health in EU Member States and neighbouring countries, together with in-

ternational partners committed to the fight against HIV/AIDS, the European Commission, the Minister of Economic Cooperation and Development and the Minister of Education and Research;

4. "Resolution 1536 (2007)1 HIV/AIDS in Europe", adopted by the Parliamentary Meeting of the Council of Europe in January 2007.

Italy has applied these documents' indications and measures for prophylaxis and care, also extending them to the foreign population [3-6]. In particular, the country is committed to:

- continuing to provide information on preventing sexual transmission (homosexual and heterosexual);
- promoting HIV testing and pre- and post-test counselling;
- providing information by involving associations for the fight against AIDS and the various ethnic groups in Italy, as well as through peer education;
- ensuring the proper training of healthcare workers, also with regard to the psycho-sociological issues faced by seropositive individuals;
- guaranteeing out-of-hospital care for chronic patients, an increasing number of whom are seeking out-patient and day-hospital care.

The European Parliament Resolution of 20 November 2008 on HIV/AIDS addresses the issue of early diagnosis and timely care. In particular, it invites the Council and the European Commission to:

- promote early diagnosis;
- guarantee timely treatment and provide information on its benefits;
- guarantee the close surveillance on the part of the European Centre for Disease Prevention and Control, including accurate estimates of the undiagnosed population (*e.g.*, quantity, characteristics), respecting privacy and the protecting personal data;
- guarantee access to testing, which must remain free of charge and anonymous.

At the local level, these actions can be ensured by centres for HIV testing and counselling, which could contribute to: decreasing the number of persons who do not return for their test results, increasing the adoption of behaviours for preventing HIV transmission among persons who become aware of their seropositivity, developing counselling strategies for preventing HIV transmission by persons living with HIV, and diagnosing comorbidities. Later in this chapter, we will discuss these issues, which are addressed in the decree with which Italy's national system for the surveillance of new diagnoses of HIV infection was established.

LEGAL ASPECTS

The administrative provisions issued by Italy since the onset of the AIDS epidemic have consisted of ministerial memorandums, which have identified

measures for epidemiological surveillance, have formulated a case definition for adults and children in accordance with international indications, and have defined how disease reporting should be carried out, guaranteeing maximum data privacy.

The Ministerial Decree of 15 December 1990 (published in the *Official Gazette* of 8 January 1991, no. 6), with which the infectious-disease surveillance system was established, defines the list of infectious diseases subject to mandatory reporting in Italy, dividing them into five classes, and it establishes the means of reporting these data [7]. With regard AIDS reporting, the Decree makes reference to the Ministerial Memorandums of 13 February 1987 (no. 5) and 13 February 1988 (no. 14) [8, 9]. These memorandums were followed by others, in which the case definition was updated and the right to data privacy was confirmed, specifying that data must refer exclusively to full-blown and confirmed cases, according to international criteria. Seropositive individuals must be safeguarded so that they receive adequate care and be referred to Regional reference centres.

Access to testing is defined by Law 135 of 5 June 1990 (published in the *Official Gazette* of 8 June 1990, no. 132). This law established the "Program of urgent interventions for the prevention of and fight against AIDS". In particular, it establishes most of the public health interventions and health-planning activities necessary for controlling the disease. This law provides for those surveillance and prevention activities that continue to be valid today, in particular, "interventions lasting many years regarding prevention, information, research, epidemiological surveillance, and the support of volunteer activities"; it addresses funding for improving infectious disease units and laboratories, and the hiring and training of technical and health personnel. With regard to training, Italy's Regions and Autonomous Provinces are required to guarantee training in HIV/AIDS to healthcare and technical personnel working in infectious disease units.

In Article 5 of this law, which regards HIV testing, ethical norms are addressed, with the aim of avoiding the discrimination and marginalisation of infected persons. In particular, Article 5 indicates that healthcare workers must provide the necessary care to persons with HIV infection and AIDS and must safeguard their privacy. Article 5 also clearly indicates that testing cannot be performed without the consent of the individual, unless it is clinically necessary and in the individual's best interest. In Article 5, the issue of divulging the results of diagnostic tests, whether directly or indirectly, is also addressed; in particular, the result of a test can only be given to the person tested. With regard to statistical data on HIV infection, testing can only be performed if the samples to be analysed are anonymous and it is impossible to identify the individual. Finally, it is specified that HIV infection must not constitute a reason for discrimination in any social or work environment [10].

The main aspects of the safeguarding of privacy with regard to HIV testing, which are stipulated in Law no. 135 of 1990, can be summarised as follows:

- HIV testing is a voluntary act for which it is necessary to obtain the explicit consent of the person being tested, who must be informed of the significance of both the test and the result;
- hospitalisation does not authorise healthcare workers to perform testing on patients;
- persons undergoing testing have the right to remain anonymous;
- the result of the test must only be divulged to the person tested, and not by telephone or mail;
- for minors, consent for testing must be provided by a parent or legal guardian;
- for incarcerated persons, testing can only be performed with the consent of the individual;
- employees and persons being considered for employment cannot be asked to undergo HIV testing;
- HIV testing cannot be performed during medical examinations for military service or during military service itself.

Articles 5 and 6 of Law 135 of 1990 is in contrast to Article 32 of the Italian Constitution, according to Decision no. 218 of 23 May – 2 June 1994 of the Constitutional Court, which considered to be well founded the question of legitimacy raised by the magistrate of Padova during civil proceedings involving a professional who was responsible for caring for non self sufficient persons and her employer. In fact, the Constitutional Court, though recognising the important social principles included in the previous articles, highlighted that Law 135 of 1990 was in contrast to the Constitution, in the section that does not address the issue of carrying out health controls without the consent of the individual (yet respecting privacy) for persons conducting work activities that may constitute a risk of transmission to others. The decision of the Constitutional Court was not followed by a legislative intervention to modify Law 135 of 1990.

At the time, the Ministry of Health, in compliance with this law, issued decrees to define national epidemiological surveillance systems for AIDS cases and the collection of statistical data on HIV infection.

Over the years, the epidemiological situation of HIV infection and AIDS has drastically changed, and all EU countries have developed specific surveillance systems for HIV infection, given that the systems for reporting AIDS were no longer sufficient for monitoring the epidemic, in that they do not provide accurate data on the main modes of transmission, that the interval of time between acquisition of the infection and clinical onset of disease has increased, and that the data cannot be used for prevention. More importantly, in order to provide therapy to asymptomatic HIV-infected persons and for therapy to be effective in delaying the disease, guaranteeing longer survival and improving

the quality of life, it is necessary to know the initial (and not the terminal) status of the disease.

The national surveillance system in Italy was established with the Ministerial Decree of 31 March 2008 (published in the *Official Gazette*, general series, no. 175). The reporting of incident cases of HIV infection has been included in the list of Class III infectious diseases, established by the Ministerial Decree of 15 December 1990, that is, diseases subject to specific surveillance, in particular, AIDS, tuberculosis, and malaria [11].

Diverse factors led to the decision to pass a decree on the reporting of new cases of infection, including, in addition to those mentioned above: the need for knowledge on this “hidden” phenomenon, which could lead to an increase in new infections; the increasing mobility from highly endemic countries; and the need to rationalise the active offering of HIV testing.

The mandatory reporting of new HIV infections will allow both general and specific epidemiological and public-health objectives to be reached; in particular:

- to improve health planning for facing the epidemic;
- to develop and evaluate targeted preventive measures and policies for safeguarding the health of seropositive persons;
- to predict the healthcare burden;
- to evaluate the incidence and prevalence of HIV infection by monitoring temporal and geographic trends;
- to study the socio-demographic, epidemiologic, and clinical characteristics of recently infected individuals;
- to study the spread of infection in different populations and population groups; and
- to use the data from surveillance systems as indirect indicators of the impact of preventive measures at both the national and local level.

This choice also took into consideration international indications, so that the data collected would be as comparable as possible to the data collected by the Eurosurveillance system, as requested on various occasions by the European Commission and in the recommendations of diverse organisations involved in the control of HIV infection and AIDS, that is, WHO, ECDC and UNAIDS.

The decision to develop this surveillance system in Italy was shared with experts in the field of the National AIDS Commission for the Fight Against AIDS, the National Health Council, the Council of Associations for the Fight Against AIDS, and, in light of the decentralisation of the National Health Service, Italy’s Regions and Autonomous Provinces. With regard to the latter point, Article 117 of the Constitutional Law of 18 October 2001, no. 3, modifies Title V of the Constitution, extending Regional responsibilities in the area of safeguarding health, whereas the State is responsible for determining the fundamental principles [12].

The decree that established the surveillance system for new HIV infections includes technical annexes which provide indications on the data to be collected, data flow, the modes of data transmission respecting security measures specified by the code for the protection of personal data (Legislative Decree of 30 June 2003, no. 196), and some recommendations regarding access to HIV testing [13]. It is expressly stated that the facilities participating in the surveillance system must be public facilities that possess the necessary requirements for performing diagnoses, counselling, and managing seropositive individuals.

This decree also provides indications on performing HIV tests, in particular, access to testing, divergence of the test result, costs of the tests, application of a ticket, and guaranteed pre- and post-test counselling, in that these aspects had not been addressed in Law 135 of 1990. The decree specifies that the test must be by anonymous, free-of-charge, and with direct access. Testing by accredited public centres must be performed through direct access, in other words, if the user presents to a public facility to undergo testing without a doctor's prescription, the prescription can be substituted by a prescription made by the facility.

Testing for HIV infection is one of the prophylaxes included in the Ministerial Decree of 1 February 1991 (published in *Official Gazette* no. 32 of 7 February 1991 and successive amendments), which redefines those health conditions for which individuals are exempt from health expenditures. The reason for the exemption is that the individual may have had at-risk behaviour or accidental exposure in the workplace [14].

In the technical attachment to the decree that established the HIV surveillance system, it is stressed that the test result must be provided to the individual by personnel trained in counselling. In particular, when the test result is provided, information must be provided on the following:

- characteristics of the infection;
- the meaning of "window period";
- the risk of infection related to behaviours;
- the appropriateness of undergo periodic testing.

If the test result is positive, then the patient should be referred to specialised centres.

Healthcare workers involved in caring for and treating seropositive persons must be provided with adequate training. For this reason, the decree's technical attachment specifies that there will be a series of periodic meetings at the national level with regional and provincial reference persons for surveillance, so as to ensure continuous updating of the results of epidemiological surveillance, the necessary interventions, and the effectiveness of the programs adopted.

The adoption of a surveillance system will have to be supported by a series of actions geared towards providing incentive for undergoing HIV testing. Based on the annual expenditure for serological HIV

tests, it has been estimated that the number of HIV tests performed has stabilised at approximately 9 million (data from 2005 and 2006) (Suligo B. Personal Communication. Roma, 2007). The reasons for the low prevalence of HIV testing in Italy could be related to that fact that infected individuals still suffer from strong social stigmatisation. Moreover, in Italy, the modalities of access to the anti-HIV antibody test do not seem to be uniform among Regions, and no data are available on the modes or procedures used in transfusion centres, which intercept a large number of persons, who, for the above mentioned reasons, go to these centres also for the sole reason of undergoing HIV testing.

For the above-mentioned reasons, effective strategies for facilitating access to HIV screening must be developed at the central and local level, as must intervention models (pre- and post-test counselling, creation of a network among facilities) targeting the general population and specific population groups. Because they have direct contact with the individual, hospital physicians and general practitioners can play a fundamental role in HIV testing (and thus in prevention and early diagnosis) by guaranteeing adequate pre- and post-test counselling and referring individuals to qualified care facilities.

In light of the indications in the Declaration of Dublin of February 2004, the National AIDS Commission identified actions to be undertaken to facilitate access to HIV testing, including activities to be performed by outpatient HIV testing and counselling centres. These centres can contribute to the following:

- increasing the number of persons who decide to undergo testing;
- decreasing the number of persons who do not return for the test results;
- follow-up of persons with at-risk behaviour, even if seronegative;
- early and pre-symptomatic diagnosis;
- early diagnosis of comorbidities;
- early adoption of safe behaviours by susceptible persons;
- adoption of counselling strategies for preventive measures geared towards persons who become aware of being seropositive;
- adequate and early therapy;
- follow-up of patients who are not yet being treated.

In light of the role played by outpatient centres for HIV testing and counselling, the Istituto Superiore di Sanità, in collaboration with the Ministry of Welfare and the Council of Associations for the Fight Against AIDS, is conducting a research project to develop intervention models for improving adherence to HIV testing, through access to the facilities available nationwide. The specific objectives of the project are to perform a comparative analysis of accessibility to HIV testing in public clinical-diagnostic facilities and in blood transfusion centres in Italy, to identify factors that contribute to decreased access to testing for at-risk populations, and

to define good practices that can be adopted by all of Italy's Regions while at the same time respecting their autonomy.

In the session of the Assembly of 26 May 2009, the Italian Government accepted a series of parliamentary motions regarding initiatives for the prevention and treatment of HIV infection and AIDS. The initiatives range from the adoption of preventive measures, health education, care, and treatment, to the promotion of information and prevention campaigns in collaboration with general practitioners and specialists and involving secondary school teachers and associations for the fight against AIDS. With regard to HIV testing, a clear need was expressed for the development of promotional campaigns for the general population and the most vulnerable population groups. For example, it was requested that the National AIDS Commission develop national guidelines to:

- guarantee, promote, and facilitate access to testing; and
- define clear tools and innovative means for guaranteeing informed access.

It was also requested that standardised procedures for proposing testing be developed for admission to hospitals and detention centres and for immigrants entering the country, and in situations of hardship, for example, in the presence of psychiatric disorders. Also reaffirmed was the need to respect regulation no. 8 of the Resolution of the European Parliament approved on 6 July 2006 regarding all forms of discrimination against seropositive persons [15], which was reaffirmed in the most recent resolution of 20 November 2008 [16].

Any future indications regarding access to HIV testing must take into account the essential cornerstones, that is, scientific evidence, information, informed consent, and the right to privacy. Regarding informed consent, there exist various pieces of legislation, first of all, Italy's Constitution, which, in Article 32, sanctions that no one can be obligated to undergo treatment if not mandated by law, which is consistent with the fundamental principle of the inviolability of personal freedom (Article 13). The provision of Article 5, paragraph 3, of Law 135/90, explicitly defines that no one can be subjected to, without their consent, HIV testing, if not for clinical reasons in the interest of the individual. However, Article 5 does not specify the conditions that constitute clinical necessity; nor does it specify whether or not reference can be made to Articles 50 and 54 of the penal code, which mandate, respectively, the consent of the individual and the conditions for determining medical necessity [17, 18].

Another point that is not covered in Law 135/90 is how to address informed consent for minors, with regard to both testing and the divulging of the test results. For minors, who in Article 2 of the civil code are considered as "incapable of acting", consent for medical treatment and intervention is the

responsibility of the parent or legal guardian, who are responsible for the care of the minor (Article 30 of the Constitution and Articles 316/357 of the civil code). With regard to informed consent for minors, the most recent ethical code of the medical profession (2006), establishes, in Article 37, that consent for diagnostic and/or therapeutic interventions for minors and the handling of sensitive data must be provided by the parent or legal guardian. However, Article 38 establishes that the physician is obligated to provide adequate information to the minor and to take into consideration his/her willingness (compatible with the minor's age), capacity to understand, and degree of maturity [19].

The ethics code of the medical profession is based on the Oviedo Convention on Human Rights and Biomedicine of 1997. In fact, the Convention specifies that no one can be subjected to medical treatment without the individual's consent. Specifically, in Article 6 it is stated that "The opinion of the minor shall be taken into consideration as an increasingly determining factor in proportion to his or her age and degree of maturity". Moreover, "where, according to law, a minor does not have the capacity to consent to an intervention, the intervention may only be carried out with the authorisation of his or her representative".

Before the Oviedo Convention there existed the UN Convention of 1989 on the Rights of the Child, which addresses the issue of informed consent for minors. However, no indications are provided on how to actually obtain consent. There also exists the Charter of Fundamental Rights of the European Union, which introduces the concept of the right to "free opinion" expressed by the minor in relation to age and degree of maturity. The same concept is addressed in the Convention on the Rights of the Child of New York of 1989, which addresses minors' right to have their opinions heard in both legal and administrative proceedings. The minor's right to information is addressed in the European Convention on the Exercise of Children's Rights of Strasbourg of 1996.

In Italy, minors are considered, from a legal point of view, incapable of acting, though in certain cases decisional autonomy is granted, for example, for the use of contraceptive drugs, abortion, and drug-dependency treatment. There has been progressive recognition on the part of Italian legislators of the minor's right to self-determination, for example, the law on voluntary abortion of May 22, 1978, no. 194, and the laws on drugs (Decree of the President of the Republic of 9 October 1990, no. 309). A minor can undergo voluntary abortion if authorised by a judge, even in the absence of a legal guardian or against the wishes of the legal guardian. The law on drugs establishes that anyone, including minors, can request diagnostic testing and treatment programs from the appropriate public facility; with specific regard to minors, the request can also be made by the legal guardian [20, 21].

CONCLUSIONS

The above considerations highlight the need for laws or univocal national indications that take into consideration the degree of maturity of the minor and the role of family relations. It is thus necessary to develop national recommendations on appropriate methods for considering the diverse phases of access to testing (pre- and post-) in relation to the level of awareness of the minor, the outcome

of the test, the divulging of the test result, and the information on health status and therapy, also in consideration of the assistance of other professional figures, such as social workers, nurses, and psychologists [22].

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