

## An improved data-collection form for the surveillance of HIV infection in Italy

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### Abstract

**Background:** The data-collection form used for Italy's recently established national HIV surveillance system does not include sufficient information to thoroughly describe the dynamics of the epidemic. In addition, comparisons with data from other European countries are difficult. To address this issue, we have developed a more detailed form based on forms used in other European countries.

**Methods:** Data-collection forms used in other countries were evaluated, and the information collected was categorised by topic. Based on this evaluation, a form was developed for use in Italy.

**Results:** The forms used in other countries are more detailed than the Italian form, and we propose adding the following information to the Italian form: i) the year of entry in Italy for non-nationals; ii) testing pattern (i.e., the number of tests in the previous two years and during lifetime); iii) whether or not infection was recent, based on the antibody avidity index, and which test and cut-off were used; iv) whether or not testing was performed in the acute phase of infection, based on symptoms; and v) a checklist of reasons for undergoing testing. We also added a "Comments" section for information not recorded elsewhere on the form.

**Discussion:** The more detailed form will allow for a more thorough description of the characteristics of newly infected persons and of the dynamics of the epidemic in Italy, which is fundamental for prevention and control initiatives. It will also allow for comparisons to be made against data from other European countries, revealing important similarities and differences.

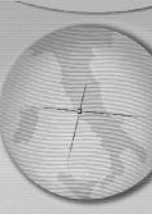
*Key words: HIV, AIDS, surveillance*

### Introduction

Until recently, in Italy, HIV infection was not subject to mandatory notification, and no national surveillance system for new diagnoses existed, so that Italy, together with Spain, were the only two countries in Europe without such a system [1, 2]. However, regional and provincial surveillance systems have existed for a number of years [3-5], and they provide essential information on the HIV epidemic in Italy. According to these data, the incidence of infection peaked at the end of the 1980s, followed by a progressive decrease until the end of the 1990s. Afterwards, the number of new infections stabilised, although in recent years it appears to have increased in certain areas. In 2008, the incidence in the areas where surveillance systems are active was 6.7 per 100,000 population, which, if generalised to Italy's entire population, would be considered as a mid-

level incidence compared to other European countries [1]. Moreover, whereas 10 or 20 years ago the most affected population groups were young persons and drug users, today the infection mainly affects mature adults, who acquire infection through sexual contact.

However, in addition to the fact that the regional and provincial systems only cover around 40% of the national population, they differ in terms of data flow, the types of centres providing data, and the data-collection forms [6], making comparisons difficult, which consequently hinder attempts to describe in detail the characteristics of the epidemic at the national level. In light of these considerations, in March 2008, Italy's Ministry of Labour, Health, and Social Policy issued a decree that created a national system, adding HIV infection to the list of Class III infectious diseases, which are subject to mandatory notification. The



decree specifies the objectives of the system, the case definition, and the way in which the system should function (e.g., the data to collect and the data flow), and it stresses the need to facilitate access to HIV testing and to provide continual training to healthcare workers in this field. The decree also proposes an individual data-collection form (Figure 1), yet this form only contains the minimum information necessary for monitoring the trend and the characteristics of new HIV diagnoses, in particular: year of birth, nationality, province of residence, gender, date of the most recent negative HIV test result, date of the first positive test result, exposure category, CD4 count (including the date it was measured), first viral load and date, clinical stage, and reason for undergoing HIV testing. It does not contain such information as the year of entry in Italy for non-nationals, data for ascertaining recent infections, or data on the presence of acute infection, all of which can be important for gaining a better understanding of the HIV epidemic and for better targeting prevention and control initiatives.

To address this issue, a more detailed data-collection form has been developed. To allow the data to be uniform with respect to data from other European countries, information was collected on the national data-collection forms used in Europe for HIV surveillance. Presented in this paper, a description of the proposed form for Italy and the forms used in other countries.

### Methods

Reference persons in 27 EU countries and the 4 EFTA countries were contacted. The data-collection forms used in other countries were provided by these reference persons (for 6 countries) (in most cases the Director of the country's national AIDS centre or HIV surveillance system) or were downloaded from the Internet (for 14 countries). We succeeded in obtaining information from 20 of the 31 countries (overall response rate of 64.5%).

We asked these reference persons to provide the forms in English; when this was not possible, the forms were translated. The data collected on these forms was then categorised by topic: demographic, clinical, virological, and immunological data; mode of acquisition of infection; presumed place and date of infection; behaviour; testing pattern; and detailed reasons for undergoing testing.

### Results

The information contained on the data-collection forms in European countries is

summarised in Table 1. Of the 31 countries contacted, 20 provided us with a copy of the form. The information was divided into 6 categories, as follows:

- 1) *Demographic, clinical, virological, and immunological data.* These data are collected by all of the countries considered and include: gender; date and place of birth; nationality; country of citizenship, official residence and actual residence; level of education; profession; marital status; clinical stage; CD4 count; and viral load. In nine countries, additional information is collected for non-nationals, such as the country of origin and the number of years of residence in the host country.
- 2) *Mode of acquisition of infection (exposure category).* This information is also included on the forms of all of the countries considered, and a similar classification is used, in particular: heterosexual, homosexual, bisexual, injecting drug user, vertical transmission, transfusion, accidental exposure, and other.
- 3) *Presumed place and date of infection.* In 18 countries, the data-collection form includes information for determining the contribution of travel or sexual tourism to the epidemic and it contains such questions as: "Where (country) do you think you were infected?"; "When do you think you were infected?"; and "Did you have sexual contact during your stay in another country?". Only France and England perform tests that allow individuals infected in the previous six months to be identified, using new laboratory methods; thus the data-collection forms used in these countries include an item on recent infections. In another four countries, the data-collection forms include an item for indirectly identifying the date of infection (recent infections), based on the presence of acute infection, which is defined if symptoms are present.
- 4) *Behaviour.* In some countries, in addition to the exposure category, the data-collection forms include specific questions on sexual behaviour. These questions focus on sexual orientation (seven countries) ("Did you have sexual contact with: a person of the opposite sex, of both sexes, of the same sex?") and other aspects of sexual behaviour: being a sex worker (five countries) ("Have you provided sex for money?"); being a client of a sex worker (five countries) ("Have you been the client of a sex worker?"); number of sexual partners in lifetime (two countries) ("How

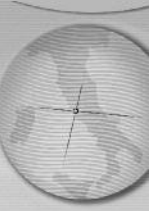


Figure 1. Data-collection form for the HIV surveillance system in the 2008 Ministerial Decree.

**SURVEILLANCE SYSTEM FOR HIV INFECTION**  
Data-collection form

Encrypted code of individual Code of diagnostic centre

Year of birth | | | | Nationality \_\_\_\_\_

Province of residence \_\_\_\_\_ Sex: M  F

Date of last negative HIV-test result: Date of first positive HIV-test result:

|day|month|year| |day|month|year|

Mode of transmission:

- Homosexual/bisexual contact <input type="checkbox"/>	- Undetermined risk <input type="checkbox"/>
- Injecting drug use <input type="checkbox"/>	- Transfusion <input type="checkbox"/>
- Heterosexual contact <input type="checkbox"/>	- Other (specify) _____
- Vertical transmission <input type="checkbox"/>	

First CD4 cell count: \_\_\_\_\_ Date of first CD4 cell count: |day|month|year|

First viral load:

- Result: \_\_\_\_\_ - Cut-off: \_\_\_\_\_

Date first viral load measured: |day|month|year|

Clinical stage (1993 CDC classification):

A1 <input type="checkbox"/>	B1 <input type="checkbox"/>	C1 <input type="checkbox"/>
A2 <input type="checkbox"/>	B2 <input type="checkbox"/>	C2 <input type="checkbox"/>
A3 <input type="checkbox"/>	B3 <input type="checkbox"/>	C3 <input type="checkbox"/>

Reason for undergoing testing: \_\_\_\_\_

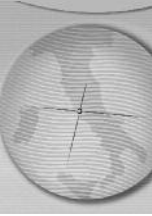
Date form completed: |day|month|year|

Date received by Regional Coordinating Centre: |day|month|year|

many sexual partners have you had in recent years?"). Moreover, in most 16 countries, information is collected on the sexual partner, in particular: stable partner, occasional partner, sex worker, HIV-positive partner, injecting drug user, non-national partner, and non-national partner from an area

that is endemic (specify country). For cases of vertical transmission, in five countries information is collected on the mother's mode of acquisition of infection.

5) *Testing pattern.* Some countries collect information on the individual's pattern of HIV testing. The most commonly used items are:



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**Table 1. Information included on data-collection forms for HIV surveillance in Europe, by country.**

	Belgium	Czech. Rep.	Denmark	Estonia	France	Germany	Greece	Hungary	Italy*	Latvia	Netherlands	Norway	Poland	Portugal	Scotland	Slovakia	Slovenia	Spain*	Sweden	Switzerland	UK	
<b>Demographic, clinical, virological, and immunological data</b>	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
If non-national, country of origin, date of entry in host country	X		X		X	X				X	X	X					X		X			
<b>Mode of acquisition (exposure category)</b>	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
<b>Presumed place and date of infection</b>	X		X		X	X	X	X	X	X	X	X	X	X	X		X	X	X	X	X	X
- recent infection, test used, cut-off					X																	X
- acute infection (presence of symptoms)			X								X	X		X								
<b>Behaviour</b>																						
Sexual orientation	X		X	X						X					X		X				X	
Sex worker							X					X		X				X				X
Client of sex worker			X				X					X									X	X
Number of sexual partners in lifetime															X						X	
Characteristics of sexual partner	X	X	X		X	X	X	X		X	X	X	X	X	X		X	X			X	
If maternal transmission, mode of acquisition of mother		X						X					X	X			X					
<b>Testing pattern</b>			X		X	X					X	X		X			X	X			X	X
<b>Detailed reason for undergoing testing</b>	X				X		X			X		X	X	X	X			X				

\*no national system for HIV case reporting

“number of tests performed in the past two years”; “test ever performed in lifetime”; “number of tests with a negative result”; “date of the most recent negative test”; and “date of the first positive test”.

- 6) *Detailed reasons for undergoing testing.* In nine countries, the reasons for which the individual underwent testing are investigated, in particular: “sexual contact with someone known to be HIV positive”; “sexual contact with a person whose serostatus was unknown to the individual”; “accidental contact with blood”; “test offered by a service for drug users”; “test performed during pregnancy”; and “test performed in a correctional facility”.

Based on the evaluation of the various data-collection forms and discussions with experts in the field and regional reference persons, a more detailed form was developed for use in Italy (Figure 2). In particular, the inclusion of the following items were proposed:

- i) the year of entry in Italy for non-nationals;
- ii) additional data on testing pattern (i.e., the number of tests in the previous two years and during the individual’s lifetime);
- iii) whether or not infection was recent (“yes”; “no”; “not determined”), based on the antibody avidity index [7], and which test and cut-off value were used;
- iv) whether or not testing was performed in the acute (or initial) phase of HIV infection (“yes”; “no”), based on the presence of symptoms;

- v) a detailed checklist of reasons for undergoing HIV testing. In addition to these items, we have also added a “Comments” section, in which the diagnosing physician can provide information that was not possible to record elsewhere on the form.

The above items are those that experts and regional reference persons unanimously agreed upon for inclusion in the form. Other items, though included on the forms in other countries, have not been included because consensus was not obtained.

### Discussion

The data-collection forms used in other European countries are much more detailed than the form used in Italy. In particular, for the sake of simplicity, only data considered to be indispensable are collected. However, these data do not provide a complete description of the characteristics of HIV-infected individuals, nor do they allow epidemic trends to be adequately monitored, and this information is fundamental for targeted control and prevention initiatives. Moreover, the lack of more complete data hinders comparisons with other countries.

With regard to the year of entry in Italy of non-nationals, this information, if cross-checked with the presumed year of acquiring infection (inferable based on the antibody avidity index and the clinical stage of infection), contributes to establishing whether or not the individual acquired infection in the country of origin or in

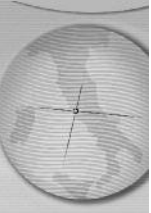


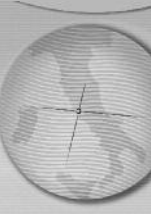
Figure 2. Proposed data-collection form for the HIV surveillance system.

NATIONAL SURVEILLANCE SYSTEM OF HIV INFECTIONS										
Encrypted code of individual <div style="border: 1px solid black; display: flex; justify-content: space-between; width: 100%; height: 15px; margin-bottom: 5px;"></div> <i>{1st and 3rd letters of surname; 1st and third letters of give name; date of birth (day/month/year), sex}</i>										
Sex:    M <input type="checkbox"/> F <input type="checkbox"/> Province of residence _____ Nationality _____ <i>For non-nationals: year of entry in Italy</i> 0000	Year of birth 0000 <i>year</i> Date of last HIV test with negative result: 00 00 0000 <i>day/month/year</i> Number of tests undergone in the last two years 00 Number of tests undergone in lifetime 00									
Date of first positive HIV-test result: 00 00 0000 <i>day/month/year</i>	Recent infection <input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> Not determined Test used _____ Cut-off _____									
Mode of transmission (possible to check more than one response) <input type="checkbox"/> Injecting drug use <input type="checkbox"/> Homosexual contact <input type="checkbox"/> Bisexual contact <input type="checkbox"/> Heterosexual contact <input type="checkbox"/> Vertical transmission <input type="checkbox"/> Transfusion/administration of coagulation factors <input type="checkbox"/> Not determined <input type="checkbox"/> Other (specify) _____	First CD4 cell count 0000/mm <sup>3</sup> Date of first CD4 cell count: 00 00 0000 <i>day/month/year</i> First viral load _____(copies/ml) Date first viral load measured: 00 00 0000 <i>day/month/year</i> Cut-off _____									
Acute infection <input type="checkbox"/> YES <input type="checkbox"/> NO	Clinical stage (1993 CDC classification) <table style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 33%; border-right: 1px solid black;">A1 <input type="checkbox"/></td> <td style="width: 33%; border-right: 1px solid black;">B1 <input type="checkbox"/></td> <td>C1 <input type="checkbox"/></td> </tr> <tr> <td style="border-right: 1px solid black;">A2 <input type="checkbox"/></td> <td style="border-right: 1px solid black;">B2 <input type="checkbox"/></td> <td>C2 <input type="checkbox"/></td> </tr> <tr> <td style="border-right: 1px solid black;">A3 <input type="checkbox"/></td> <td style="border-right: 1px solid black;">B3 <input type="checkbox"/></td> <td>C3 <input type="checkbox"/></td> </tr> </table>	A1 <input type="checkbox"/>	B1 <input type="checkbox"/>	C1 <input type="checkbox"/>	A2 <input type="checkbox"/>	B2 <input type="checkbox"/>	C2 <input type="checkbox"/>	A3 <input type="checkbox"/>	B3 <input type="checkbox"/>	C3 <input type="checkbox"/>
A1 <input type="checkbox"/>	B1 <input type="checkbox"/>	C1 <input type="checkbox"/>								
A2 <input type="checkbox"/>	B2 <input type="checkbox"/>	C2 <input type="checkbox"/>								
A3 <input type="checkbox"/>	B3 <input type="checkbox"/>	C3 <input type="checkbox"/>								
Reason for undergoing testing: <input type="checkbox"/> Symptoms suggestive of HIV infection <input type="checkbox"/> Sexual contact with person with unknown serostatus <input type="checkbox"/> Sexual contact with HIV-positive person <input type="checkbox"/> Control for donation (blood/organ/tissue/sperm) <input type="checkbox"/> Accidental contact with blood <input type="checkbox"/> Gynaecological control or control during pregnancy <input type="checkbox"/> Control for suspected STD <input type="checkbox"/> Test offered by drug-dependency centre <input type="checkbox"/> No known risk factor <input type="checkbox"/> Other (specify) _____										
Physician's comments ..... ..... .....										
Date form completed: [day]month[year] Date received by Regional Coordinating Centre: [day]month[year]										
Code of diagnosing centre <div style="border: 1px solid black; display: flex; justify-content: space-between; width: 100%; height: 15px; margin-top: 5px;"></div>										

Italy, and it is fundamental for understanding the dynamics of the epidemic in this particularly vulnerable population group. This is of particular importance if considering that, according to the regional and provincial surveillance systems, the

proportion of HIV-infected individuals represented by non-nationals has been progressively increasing in recent years [3].

Regarding the pattern of HIV testing, although the dates of the most recent negative test result



and the first positive result are already included on the existing form, the addition of the number of tests performed in the previous two years and during the individual's lifetime provides us with an idea of the frequency of testing and thus the probability of identifying new diagnoses of HIV infection. The frequency of testing also allows us to evaluate individuals' attitudes toward testing and to interpret the incidence observed in diverse population groups.

The information on whether or not infection was recent is important because, using the antibody avidity index, it is possible to establish if infection was acquired in more or less the previous six months [7], and, depending on the type of test used and the cut-off value, the actual incidence of HIV infection at the population level can be estimated. The ECDC recently recommended that this information be included in all surveillance systems in Europe [8]. Similar information is provided by the question on whether testing was performed in the acute (or initial) phase of infection, based on the presence of symptoms.

Whereas the form in the ministerial decree only includes a blank space for writing the reasons for undergoing HIV testing, the checklist of reasons allows more detailed information to be collected, and it facilitates comparison with other databases. Finally, the importance of the "Comments" section lies in the fact that it allows the diagnosing physician to provide additional information that was not possible to record elsewhere on the form,

making a more accurate description of the individual possible.

Although some European data-collection forms are even more detailed than the one we propose, and despite our opinion that the form in the ministerial decree does not contain sufficient data, we believe that it is important to keep the form relatively brief, so as to minimise the burden for individuals who undergo testing and for healthcare personnel. The addition, in inclusion of the above items to the data-collection form will allow us to more thoroughly describe the characteristics of infected individuals, as well as the trend and actual incidence of infection at the national level, which is important for the purposes of public-health initiatives such as prevention and control campaigns and for health planning in general. The use of this form will also allow the data from Italy to be compared with data from other European countries and to reveal differences in the dynamics of the epidemic. As a final note, with particular relevance to Italy, due to regionalisation of the National Health System, each region is now able to develop its own surveillance system and use its own data-collection form. The adoption of the proposed form will allow the data collected by the various systems to be compared.

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