

## ORIGINAL ARTICLE

# Epidemiological and clinical characteristics and behaviours of individuals with newly diagnosed HIV infection: a multicentre study in North Italy

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## Key words

HIV • Sexual behaviour • Condom

## summary

**Introduction.** We aimed to investigate socio-demographic, clinical and epidemiological characteristics and behaviours of subjects with new HIV diagnosis.

**Methods.** We carried out a multi-centre cross-sectional study comprising 17 Infectious Diseases Units in the Lombardy Region, North Italy. All subjects with a first positive test for HIV infection examined in 2008-09 were interviewed using a structured questionnaire.

**Results.** 472 patients were enrolled (mean age 39.8 years, standard deviation [SD] 11.5), mostly males (78%), and born in Italy (77%). The most common routes of HIV transmission were heterosexual intercourse (49%) and sex among men who have sex with men (MSM) (40%). Never/sometimes use of a condom with occasional partners was associated with male gender, heterosexual transmission route, and with > 10 sexual partners in their

lifetime. 47% had previous HIV negative tests. Having had more than 2 previous HIV negative tests was associated with younger age, MSM transmission route, CD4<sup>+</sup> lymphocyte count  $\geq$  350/ $\mu$ l and self-perception of risk.

**Discussion.** This study shows that there is a large portion of the adult population, especially heterosexual men aged 45 years and over, who are at high risk of acquiring and transmitting HIV infection and undergoing the HIV diagnostic test late, due to risk behaviours combined with a low perception of being at risk. Compared to people infected by heterosexual contacts, MSM show a greater awareness of being at risk of infection, but this knowledge has a low impact in reducing at-risk behaviours.

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## Introduction

A total of 25,917 newly diagnosed cases of HIV infection were recorded in 2009 in Europe [1] (5.7 per 100,000 population). In Italy, 2,588 cases were reported in the same year by the National Surveillance System, covering 72.1% of the Italian population (6.0 per 100,000 population) [2]. The epidemiological characteristics of cases occurring in the past decade in Italy have changed, compared to the previous years. First, the mean age at diagnosis increased from 26 and 24 years in 1985 to 39 and 36 in 2009, in males and females respectively [2]. Second, heterosexual intercourse has become the main route of transmission, followed by sex among men who have sex with men (MSM) (75.7% for both together) [2], whereas in Europe, the majority of new HIV infections are due to sex among MSM (35%) followed by heterosexual contacts (24%) [1]. Third, the proportion of late testers (having a CD4<sup>+</sup> count < 350 cells/ $\mu$ l or AIDS diagnosis) [3] has increased to 29% [4], as in other European countries. Although recent changes in the epidemiological pattern of HIV infection have been focused on, as far as we know few studies have assessed

behavioural risk factors for subjects with newly diagnosed HIV infection [5, 6]. The purpose of this research was to describe the socio-demographic and behavioural characteristics of subjects with new HIV diagnosis.

## Methods

This multi-centre cross-sectional study covered 16 out of the 17 Infectious Diseases Units and 1 Centre for Sexually Transmitted Diseases located in the Lombardy Region, North Italy (overall population about 9 million inhabitants) [7]. Subjects with a first positive test for HIV, performed in the 90 days prior to the first visit at the collaborating centre, between 01/12/2008 and 30/11/2009, were included in this study (incident cases). The inclusion criteria were new diagnosis, HIV-infection confirmed by the Western Blot method, age  $\geq$  18 years, a good understanding of the Italian language and no cognitive impairments at diagnosis.

A questionnaire was administered to the patients by specifically trained health personnel. It contained questions about socio-demographic, epidemiological and behav-

itorial aspects (sexual behaviour, use of non-injecting drugs and HIV testing history). Clinical and laboratory data at HIV diagnosis were also collected from medical records. The clinical stage of HIV infection was defined using the 1993 CDC classification [8]. Late diagnosis of infection was defined as having CD4<sup>+</sup> count below 350/ $\mu$ l at first visit [4]. The incidence rates of HIV infection were computed using the populations reported on the website of the Italian National Statistics Institute [9]. The Ethics Committees of the coordinating centre and of the collaborating centres all approved the project.

All patients signed the informed consent form. A descriptive analysis of the characteristics of newly diagnosed HIV patients was performed using common methods for the analysis of proportions. The associations between socio-demographic, epidemiological and behavioural variables were assessed using multivariate methods. The odds ratios (ORs) were computed as estimates of the associations, fitting multiple logistic regression models adjusted for age, gender and the variables investigated. All the statistical tests were two-sided, with a threshold of 0.05 for rejecting the null hypothesis. The confidence intervals were computed at the 95% level. Statistical analyses were performed using STATA software for personal computer (Stata Statistical Software release 10.0, 2009; Stata Corporation, College Station, Texas).

## Results

472 patients selected from among the 879 eligible (53.7%) were enrolled, the average number of patients per centre being 27.8 (range 8-127 patients). Subjects had a mean age of 39.8 years (standard deviation [SD] = 11.5; range: 18-76 years). Most of them (78.0%) were male and born in Italy (76.9%), had a medium-low educational level (80.3%), were employed (71.2%) and single (56.4%).

The most common route of HIV transmission was heterosexual intercourse (48.5%), followed by sex among MSM. Almost half of the patients had had more than 10 sexual partners during their lifetime (44.9%). Of those who claimed in the interview to have a current partner, 78.8% informed him/her about their own HIV seropositivity. The majority of patients reported no or sporadic use of a condom with an occasional (56.4%) or steady (79.6%) partner. 170 patients (36.0%) reported having used one or more drugs (data not shown in tables). Almost half of the patients (46.6%) had had previous negative HIV tests in their lifetime, and 57.7% of them more than 2 tests. A high proportion of patients did not explain the reason for undergoing the present HIV testing (39.8%); among those answering the question, the most common reasons were patient's request (23.3%), general practitioner's prescription (22.5%) and concern about having been exposed (11.9%). Overall, most patients (57.6%) claimed they did not perceive themselves as being at risk of acquiring HIV infection (data not shown in tables).

The clinical and laboratory data are shown in Table I. The median value of CD4<sup>+</sup> lymphocyte count at diagnosis was 327/ $\mu$ l, and 50.2% had fewer than 350/ $\mu$ l. The majority of patients were in Class A (54.5%) according to the CDC 1993 classification, although 21.6% were in Class C. Heterosexual men were significantly different from both MSM and women as regards all the characteristics investigated (Tab. II): they showed the highest proportion of subjects aged 45 years and over, late testers, subjects who had not undergone previous HIV tests and who did not undergo tests because did not perceive themselves to be at risk, the lowest proportion of subjects who always used a condom with occasional partners, and the lowest proportion of subjects who underwent present HIV testing on their own request. On the other hand, MSM claimed to have had more sexual partners in their lifetime. Women were usually half way between hetero-

**Tab. I. Clinical characteristics and laboratory parameters of patients with new HIV diagnosis.**

Clinical characteristics	N (%)
CD4 <sup>+</sup> lymphocyte count (cells/ $\mu$ l) median (1 <sup>st</sup> and 3 <sup>rd</sup> quartile); range	
CD4 <sup>+</sup> lymphocyte count	327 (101 and 550); 1-1584
< 350/ $\mu$ l	237 (50.2)
$\geq$ 350/ $\mu$ l	212 (44.9)
NA	23 (4.9)
CDC 1993 classification (clinical categories)	
Group A (asymptomatic infection)	257 (54.5)
Group B (minor symptoms)	62 (13.1)
Group C (AIDS symptoms)	102 (21.6)
NA	51 (10.8)
AIDS defining events <sup>a</sup>	
<i>Pneumocystis jiroveci</i> pneumonia	38 (37.2)
CMV infection	24 (23.5)
Oesophageal candidiasis	18 (17.6)
Kaposi's sarcoma	12 (11.7)
Other	40 (39.2)

CDC: Centre of Disease Control and Prevention, NA: not available, CMV: *Cytomegalovirus*  
<sup>a</sup> The sum of percentages is more than 100% because more than one answer was allowed.

**Tab. II.** Demographic, laboratory and behavioural characteristics and self perception of risk of patients undergoing voluntary HIV test with sexual transmitting route of HIV infection.

Patient details	Heterosexual males (%) n = 145	Heterosexual females (%) n = 84	MSM (%) n = 186	Heterosexual males vs females p value	Heterosexual males vs MSM p value
Age (years)					
< 35	31 (21.4)	37 (44.1)	77 (41.4)		
35-44	49 (33.8)	28 (33.3)	60 (32.3)	< 0.001	< 0.001
≥ 45	65 (44.8)	19 (22.6)	49 (26.3)		
CD4 <sup>+</sup> lymphocyte count / μl					
< 350	93 (64.1)	43 (51.2)	67 (36.0)		
≥ 350	48 (33.1)	36 (42.9)	107 (57.5)	NS	< 0.001
NA	4 (2.8)	5 (5.9)	12 (6.5)		
Use of condom with occasional partner					
Always	27 (18.6)	28 (33.3)	72 (38.7)		
Never/sometimes	108 (74.5)	26 (31.0)	108 (58.1)	< 0.001	< 0.001
NA	10 (6.9)	30 (35.7)	6 (3.2)		
Previous negative HIV tests					
0	105 (72.4)	47 (55.9)	60 (32.3)		
1-2	21 (14.5)	23 (27.4)	37 (19.9)	0.018	< 0.001
> 2	16 (11.0)	14 (16.7)	86 (46.2)		
NA	3 (2.1)	0 (0.0)	3 (1.6)		
Number of sexual partners during lifetime					
≤ 10	63 (43.5)	65 (77.4)	34 (18.3)		
> 10	58 (40.0)	7 (8.3)	130 (69.9)	< 0.001	< 0.001
NA	24 (16.5)	12 (14.3)	22 (11.8)		
Reasons for present HIV testing <sup>a</sup>					
Requested by the patient	11 (7.6)	15 (17.9)	73 (39.3)	0.018	< 0.001
GP prescription	36 (24.8)	12 (14.3)	38 (20.4)	0.059	NS
Concern about possible exposure	7 (4.8)	7 (8.3)	36 (19.3)	NS	< 0.001
Other	0 (0.0)	1 (1.2)	1 (0.5)	NS	NS
NA	84 (57.9)	36 (42.9)	43 (24.2)	0.028	< 0.001
Reasons for not performing previous tests <sup>b</sup>					
No concern about risk to self	86 (81.9)	35 (74.5)	28 (46.7)	0.010	<0.001
Trust in the partner	28 (26.7)	8 (7.6)	18 (17.1)	0.050	0.012
Steady sexual partnership	6 (5.7)	6 (12.8)	9 (15.0)	NS	NS
Fear of the result	9 (8.6)	3 (6.4)	17 (28.3)	NS	NS
Indifferent/unresponsive	7 (6.7)	2 (4.2)	5 (8.3)	NS	NS
Self perception of HIV infection risk					
Yes	29 (20.0)	18 (21.4)	115 (61.8)		
No	112 (77.2)	63 (75.0)	64 (34.4)	NS	< 0.001
NA	4 (2.8)	3 (3.6)	7 (3.8)		
Self perception of previous information about HIV infection					
Yes	67 (46.2)	31 (36.9)	115 (61.8)		
No	75 (51.7)	52 (61.9)	69 (37.1)	NS	0.006
NA	3 (2.1)	1 (1.2)	2 (1.1)		

GP: general practitioner, MSM: men who have sex with men, NA: not available, NS: p>0.05

<sup>a</sup>The sum of percentages is more than 100% because more than one answer was allowed. Some subjects did not answer this question. The analysis was restricted to subjects who underwent voluntary testing (pregnancy, health examination and blood donation excluded). <sup>b</sup>The percentages are computed on the total who did not perform previous HIV tests (105 heterosexual males, 60 MSM and 47 heterosexual females). The sum of percentages is more than 100% because more than one answer was allowed.

sexual men and MSM, and differed significantly from heterosexual men for almost all variables.

The variables potentially associated with having had more than 2 negative HIV tests during lifetime using logistic regression analysis (Tab. III) included age < 45 years, MSM transmission route, higher CD4<sup>+</sup> lymphocyte count at diagnosis, greater self-perception of HIV risk and better information about HIV infection.

We found that the proportion of individuals with CD4<sup>+</sup> count < 350/μl (late testers) increased significantly with age (from 25% among subjects < 25 years to 60.4% among those aged 45 and over) and decreased with level of education (from 63.8% among patients who attended primary school to 37.8% among those with a degree), and it was higher in heterosexual men compared to MSM (66.0% vs 38.5%) and in patients with fewer than 3 previous negative HIV tests compared to those who had 3

**Tab. III.** Variables associated with having performed more than 2 previous HIV tests (No 127).

Variable	OR (95% CI) <sup>a</sup>	P value
Age (years)		
< 35	2.96 (1.42-6.19)	0.004
35-44	2.92 (1.37-6.22)	0.005
≥ 45	1	
Sexual transmission route		
Heterosexual intercourse	1	
Sex among MSM	2.95 (1.62-5.36)	< 0.001
CD4 <sup>+</sup> Lymphocyte count/ $\mu$ l		
< 350	1	
≥ 350	3.77 (2.08-6.83)	< 0.001
Self perception of HIV infection risk		
No	1	
Yes	2.49 (1.38-4.50)	0.002
Previous informations about HIV infection		
Yes	1	
No	2.66 (1.48-4.76)	0.001

<sup>a</sup> Odds ratio (OR) estimates from a logistic regression model including all the variables in the table.  
MSM: men who have sex with men

or more tests (64% vs 35.1%). Using logistic regression analysis, however, only age (OR = 2.08 for 45 years and older; 95% CI = 1.21-3.57), education (OR = 2.28 for the lowest vs the highest level; 95% CI = 1.27-4.07) and having had fewer than 3 previous HIV tests (OR = 3.67; 95% CI = 2.24-6.00) were found to be statistically significant, or near the test threshold, predictors of late HIV diagnosis (data not shown).

## Discussion

Since only 53.7% of the eligible patients participated in the study, there may have been a selection bias for HIV incident cases in the period. This seem unlikely, however, because the demographic and epidemiological characteristics of newly diagnosed HIV cases observed are in agreement with national data [10] as regards the male:female ratio (3:1 in Italy), mean age at HIV diagnosis (39 for males and 36 for females), the proportion of subjects born out of Italy (27.2%), and the main sexual route of HIV transmission (79%). We found no significant difference in the demographic characteristics of the patients enrolled at the Principal Investigator's Centre (n. 127, 26.9%) and at the other Centres.

About 1/3 of patients reported having used one or more non-injecting drugs. This proportion is higher than the estimated 6.6% of non-injecting drug users among the general population in Italy in 2008 [11]. This suggests an association between non-injecting drug use and high-risk behaviours in these subjects [12, 13].

More than half of the patients with a new HIV diagnosis were not aware of having been at risk. In fact, about half of the patients had not undergone previous HIV tests and, similarly, 50.2% of the subjects under study had a late diagnosis of the infection (CD4<sup>+</sup> lymphocyte count < 350 cells/ $\mu$ l).

Late diagnosis of HIV is currently a matter of concern, both for individuals (high morbidity and mortality) and

for public health (increased risk of transmission) [4]. Since there is no standard definition for late HIV diagnosis, we used the one based on CD4<sup>+</sup> count below 350/ $\mu$ l [3]. We found that about half of newly diagnosed HIV cases were late presenters, in agreement with North American (56%) [14] and European data [1, 15], though lower proportions were observed in other Italian and European studies [4,16]. In our research, the risk of late presentation increased with older age at diagnosis, lower education and not having had previous HIV tests, but not with transmission route, although heterosexual males are at greater risk of late diagnosis compared to MSM, according to recent European data [4, 15]. We found no differences in the proportion of late testers between males and females, in agreement with some studies [15], but in contrast to other European studies showing a higher proportion of late presenters among males [4, 14, 16] or females [1, 17]. These discrepancies may be due to the common policy of offering routine testing to pregnant women in some European countries, which allows an earlier diagnosis of HIV infection in this group, or to subject selection, especially as regards the proportion of MSM in the different male case-series.

Taken together, these findings suggest that older heterosexual men with a low level of education and with fewer than 10 partners in their lifetime, do not perceive themselves as being at risk, leading them to engage in high-risk behaviours.

Sex among MSM was the second route of transmission of HIV infection in our study. The majority of MSM engage in various high-risk sexual behaviours: most of them are younger at HIV diagnosis, never/sometimes use a condom with occasional partners and have > 10 partners in their lives, in agreement with other Italian studies concerning MSM behaviour [18]. For this reason, contrary to heterosexual men, MSM are more aware of being at risk, although they persist in high-risk behaviours. Indeed, MSM are still more widely tested for HIV than heterosexual males and females [16].

## Conclusions

In conclusion, this study shows that in Italy there is a large proportion of the adult population, especially heterosexual men aged 45 years and over, who are at high risk of acquiring and transmitting HIV infection, have a low perception

of being at risk and tend to perform the HIV diagnostic test late. This suggests that past information campaigns have focused too much on so-called "high-risk groups", i.e. intravenous drug users (IDUs) and MSM, and therefore there is an urgent need to re-address information campaigns on HIV prevention to the general population.

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