Changing blood donor screening criteria from permanent deferral for men who have sex with men to individual sexual risk assessment: no evidence of a significant impact on the human immunodeficiency virus epidemic in Italy

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Background. In 2001, the criteria for blood donor eligibility in Italy were modified by a ministerial decree from a permanent deferral for "men who have sex with men" to an individual risk assessment of sexual behaviours. The aim of this study was to evaluate the impact of this change in donor screening criteria on the human immunodeficiency virus epidemic among blood donors in Italy.

Materials and methods. We used the data obtained from the Italian blood donor epidemiological surveillance system. We compared data collected in 2009 and 2010, when the individual risk assessment policy was applied, with data collected in 1999 when permanent deferral was applied for men who have sex with men based on a declaration of sexual orientation. We evaluated the change over time in the relative proportion of HIV antibody-positive donors who likely acquired the infection from men who have sex with men *vs* heterosexual sexual exposure; the relative risk was calculated using 1999 as the reference year.

Results. In all 3 years, the majority of HIV antibody-positive donors reported sexual exposure as a risk factor for HIV infection; this proportion increased over time, although not statistically significantly. Heterosexuals always accounted for at least 40% of all HIV antibody-positive cases. The rate of HIV antibody-positive donors increased similarly in men who have sex with men and heterosexuals; specifically, the rate of HIV antibody-positive cases per 100,000 donors was more than 2-fold higher among men who have sex with men in 2009-2010 than in 1999 (2009-2010 *vs* 1999, RR =2.8; P =0.06), and that among heterosexuals was 1.5 fold higher (P =0.18).

Discussion. When comparing the period before (1999) and after (2009-2010), the implementation of the individual risk assesment policy in 2001, no significant increase in the proportion of men who have sex with men compared to heterosexuals was observed among HIV antibody-positive blood donors, suggesting that the change in donor deferral policy did not lead to a disproportionate increase of HIV-seropositive men who have sex with men.

Keywords: blood donors, HIV infection, sexual behaviour, MSM, heterosexual.

Introduction

In Italy, the human immunodeficiency virus (HIV) epidemic started in 1982 and the incidence of new HIV diagnoses peaked in 1987 (26 new cases per 100,000 residents); it then decreased until 1998 and remained stable at about six new HIV cases per 100,000 residents per year. In the last two decades, a marked decrease in the proportion of injecting drug users has been observed among new HIV diagnoses (54.3% in 1991, 4.7% in 2011), whereas the proportion of infections caused by sexual contacts has increased (heterosexuals 18.1% in 1991, 45.6% in 2011; men who have sex with men [MSM] 10.7% in 1991, 33.2% in 2011)[1,2].

In 1991, a decree of the Ministry of Health[3] updated procedures and criteria for blood donor selection in Italy. In accordance with this decree, candidate donors were asked to fill in a specific history questionnaire in order to collect any relevant information about their clinical conditions and behaviours putting them at risk of being carriers of transfusion-transmissible infections. Candidate blood donors were then interviewed face-to-face by a specifically trained physician, who was in charge of deciding the subjects' eligibility to donate blood, according to the selection criteria defined by law. The donor health history questionnaire included specific questions concerning sexual behaviour. In particular, all

male donors were asked if they were homosexual; any male who declared having ever had sex with other men was systematically permanently deferred. Heterosexuals reporting casual sexual contact with persons whose serostatus was unknown or positive for syphilis and/or HIV and/or hepatitis B virus (HBV) and/or hepatitis C virus (HCV) were permanently deferred[3].

In 2001, a new decree of the Ministry of Health[4] changed the previous provisions. A new policy was introduced based on an individual risk assessment (IRA) of candidate donors with regards to at-risk sexual behaviour. Again, by law, only specifically trained physicians - no other healthcare professionals - were allowed to evaluate blood donors and formally issue the eligibility judgment for each candidate donor. The policy envisaged that the deferral of a blood donor could not be based on the donor's sexual orientation, but had to be based on the assessment of individual declared/detected at-risk behaviour, regardless of donor's sexual orientation. Therefore, MSM donors were no longer permanently deferred because of their sexual orientation. Since then, the donor selection procedure has been implemented nationwide in accordance with the requirements settled by the national decree, and the IRA of sexual risk behaviours was applied to all blood donors, both males and females, heterosexuals and MSM.

In 2005, a further decree of the Ministry of Health[5], transposing Directive 2004/33/EC[6], confirmed the 2001 IRA policy. Before donation every blood donor fills in a questionnaire including questions regarding his/her sexual behaviour and (whenever applicable) his/her partner's sexual behaviour. The donor is then interviewed face-to-face in a private and confidential location by a specifically trained physician for further investigation and confirmation of risk exposures, and for other items concerning the donor's eligibility. The policy introduced a distinction between "risk" and "high risk" sexual behaviour to be individually assessed in each blood donor, both male and female, regardless of sexual orientation. "Risk" sexual behaviour includes: having a new sexual partner whose sexual behaviour is unknown, having ever had one occasional sexual relationship with a person whose sexual behaviour is unknown, having had casual sex with an HIV- and/or HBV- and/or HCV-infected partner. A blood donor, whether MSM or heterosexual, having engaged in any of these behaviours is deferred for 4 months from the exposing event. "High risk" behaviour is intended as a behaviour exposing the donor to a high risk of acquiring transfusion-transmissible infections and includes: usual/recurrent (occurring repeatedly) sex with more than one heterosexual or MSM partner whose sexual behaviour is unknown, receiving or exchanging sex for money, use of injecting drugs, usual/recurrent

sex with a partner positive for syphilis and/or HIV and/or HBV and/or HCV. A blood donor, whether MSM or heterosexual, having engaged in any of these behaviours is permanently deferred. The physician in charge of blood donor selection is responsible for adjudicating either "risk" or "high risk" behaviour.

Hence, sexual orientation *per se* is not and cannot be considered a criterion for deferral. In the pre-donation questionnaires adopted in 1999, 2001 and 2005, the specific type of sexual intercourse (oral, anal, etc.) was not assessed, and "safe sex", implying the use of condom, was not considered a reason for reducing any deferral period.

MSM status as such is not considered a high risk behaviour. If a male blood donor declares having sex with men, the physician responsible for donor eligibility shall include the donor in one of the following risk levels, based on his sexual behaviour: (i) not at risk (eligible), (ii) at risk (4-month deferral), (iii) at high risk (permanent deferral).

The controversies that emerged at an international level associated with deferral of MSM and IRA of donors[7] have prompted the present analysis, whose objective is to evaluate the impact of the changing donor screening criteria from permanent deferral for an MSM sexual orientation to an IRA of sexual behaviours in Italy, as regards the HIV epidemic among blood donors in Italy.

Materials and methods
Blood donor surveillance system

We used data obtained from the Italian blood donor surveillance system, which was started in 1989 by the National Institute of Health[8], coordinated since 2007 by the National Blood Centre[9], and managed by the National Blood Centre since 2009 by web-based technology through the National Blood Information System (SISTRA)[10]. Between 1999 and 2006, blood donors surveillance data were collected on a voluntary basis; in 1999 the rate of participation of Blood Transfusion Centres was 66.3%. In 2007, according to the national Decree of 9 November 2007, n. 207[11], that transposed the European Directive 2005/61/EC[12], the surveillance of transfusion-transmissible infections became part of the Italian national haemovigilance system[13] and the participation of Blood Transfusion Centres was mandatory, thus complying with European and national legislative provisions. In 2009 and 2010 the rate of participating Blood Transfusion Centres was 100%[14].

The surveillance system of transfusion-transmissible infections collected information on HCV-, HIV-, HBV- and syphilis-seropositive blood donors/donations. The notification of seropositive cases included the identification of the notifying Blood Transfusion Centre, anonymous identification of seropositive blood donor; methods used for screening and confirmatory testing,

results of tests, risk factors and at-risk behaviours in the donor's history. All Blood Transfusion Centres in Italy use the same definitions for classifying risk factors and at-risk behaviours.

Definitions of repeat and first-time/lapsed donors

Blood donors were classified as repeat donors or first-time/lapsed donors. Repeat donors included persons who donate blood and have donated blood at least once in the previous 24 months. First-time/lapsed donors included persons who donate blood without evidence of previous blood donations, persons who donate blood and have donated blood more than 24 months before[15], and persons (candidate donors) who are preliminarily tested for infectious diseases prior to a postponed first donation.

Donor eligibility and testing

A specifically trained physician investigated risk factors in both the pre-donation questionnaire and face-to-face pre-donation interview, and judged the eligibility of each donor. A donor who reported no at-risk behaviour (according to the selection criteria issued in 1991 and 2001), or denied having engaged in at-risk behaviour, was allowed to donate blood. Blood donors were screened for HIV using CE-marked screening assays, and all seropositive samples were confirmed by Western Blot. In 2008, HIV screening by Nucleic Acid Amplification Technology (NAT) became mandatory[16]; in order to enable a comparison of results before and after 2008, NAT-only-positive blood donors were excluded from analysis.

Post-donation interview

Confirmed HIV antibody-positive blood donors were admitted to a non-standardised post-donation interview performed by a trained physician, in order to investigate in-depth at-risk behaviours of the donor and of his/her sexual partner throughout life and particularly in the 4 months prior to donation. The post-donation interview also included questions concerning other risk factors such as use of injecting drugs, surgical treatments, tattooing, acupuncture and travel to HIV endemic areas. Data divided by gender were available only for 2009 and 2010. The face-to-face interview was conducted in a confidential and private setting to favour truthful answers from the donors and to reduce underreporting of socially stigmatising behaviours, including male-with-male sex. The results of the post-donation interview were available for 1999, 2009 and 2010. We, therefore, compared data collected in 2009 and 2010 (when the IRA policy was applied) with data collected in 1999 (when permanent deferral based on a declaration of MSM sexual orientation was applied)[17].

Exposure categories

We used information collected in the post-donation interview to classify HIV antibody-positive donors in four exposure categories: MSM, heterosexual, other and not determined. MSM were defined as men, both homosexual and bisexual, who declared having or having had sex with men (regardless of the partner's HIV serostatus) at least once in their lifetime. Heterosexuals included persons who declared having or having had sexual contacts at risk with persons of the opposite gender (regardless of the partner's HIV serostatus). The group defined as "Other" refers to donors who reported risk factors other than sexual risk behaviour. Donors who reported no risk factors for HIV infection were included in the group "Not determined". This classification was used since 1991.

Statistical analysis

The incidence of HIV infection among blood donors was defined as the number of HIV antibody-positive repeat donors divided by the total number of repeat donors by year. Repeat donors were counted once in each calendar year during which they donated, even if they made more than one donation. The prevalence of HIV infection among blood donors was defined as the number of HIV antibody-positive first-time/lapsed donors divided by the total number of first-time/lapsed donors by year. NAT-only-positive donors were excluded from the calculation of both incidence and prevalence.

The proportion of HIV antibody-positive MSM among blood donors was calculated using the number of HIV antibody-positive MSM as the numerator and the number of male blood donors as the denominator (per 100,000). The proportion of HIV antibody-positive heterosexuals among blood donors was calculated using the number of HIV-seropositive heterosexuals as the numerator and the number of all blood donors as the denominator (per 100,000). To evaluate the difference over time of the proportion of HIV antibody-positive MSM and the proportion of HIV antibody-positive heterosexuals, the relative risk (RR) was calculated using 1999 as the reference year.

We compared the proportion of HIV antibody-positive blood donors by year using the Chi-square test and the test of comparison between proportions. Results were considered statistically significant when P <0.05. The statistical analysis was conducted using SPSS 20.0 (IBM, Chicago, Illinois, USA).

Results
HIV incidence and prevalence
HIV incidence showed a non-statistically significant increase in 2009-2010 compared to 1999 (3.9 *vs* 3.0; P =0.23), whereas HIV prevalence showed a

slight, non-statistically significant decrease in 2009 compared to 1999 (15.5 *vs* 16.1; P =0.89) and in 2010 compared to 1999 (12.3 *vs* 16.1; P =0.35). HIV incidence in 2009-2010 was 3-fold higher among male repeat donors than among female repeat donors (4.8 per 100,000 male repeat donors *vs* 1.6 per 100,000 female repeat donors, respectively; P =0.00), while HIV prevalence was 2-fold higher among male donors than among female donors (16.7 per 100,000 male first-time/lapsed donors *vs* 8.5 per 100,000 female first-time/lapsed donors; P =0.00) (Table I). HIV incidence and prevalence were calculated excluding NAT-only-positive blood donors from the analysis; when NAT-only-positive donors were included among repeat donors (3 repeat donors in 2009, none in 2010), the incidence in 2009-2010 was 4.0 per 100,000 repeat donors. Among first-time/lapsed donors, no NAT-only-positive donors were found in 2009-2010.

Post-donation interview

All of the 218 donors confirmed as being HIV antibody-positive in 2009-2010 underwent the post-donation interview. More than one-third (35.5%) of these donors reported a sexual exposure at risk more than 4 months prior to donation, 28.5% reported no risk exposure, and 36.0% admitted to having engaged in risk sexual behaviours in the 4 months prior to donation. Among these last, the reasons for not reporting these sexual behaviours at the pre-donation questionnaire and medical interview were as follows: (i) not considering those sexual contacts at risk, (ii) underestimating the actual risk of that behaviour, (iii) thinking that the pre-donation serological screening would detect any infection. The proportion of those who admitted to having engaged in sexual risk behaviours in the 4 months prior to donation was similar among MSM (52.8%) and heterosexuals (50.0%) (P =0.94); interestingly, this proportion was significantly higher among repeat donors than among first-time/lapsed donors (64.1% *vs* 36.4%; P =0.005).

Exposure categories

Table II shows the distribution of HIV antibody-positive blood donors by year and exposure category in 1999, 2009 and 2010. In 1999, the coverage of the surveillance system for transfusion-transmissible infections was lower and the proportion of donors reporting risk factors other than sexual exposure was

Table I - Incidence and prevalence of HIV infection among blood donors by year.

Year		Repeat donors			First-Time/Lapsed donors°		
		N. of donors	N. of HIV Ab-positive donors	Incidence per 100,000 donors	N. of donors	N. of HIV Ab-positive donors	Prevalence per 100,000 donors
1999*	Total	775,357	23	3.0	93,034	15	16.1
2009	Male	1,017,941	48	4.7	237,540	44	18.5
	Female	407,850	9	2.2	131,105	13	9.9
	Total	1,425,791	57	4.0	368,645	57	15.5
2010	Male	1,026,675	51	5.0	258,206	39	15.1
	Female	414,675	4	1.0	140,908	10	7.1
	Total	1,441,350	55	3.8	399,114	49	12.3

Legend °includes candidate donors preliminarily tested for infectious markers prior to a postponed donation; *data by gender not available.

Table II - Distribution of HIV antibody (Ab)-positive blood donors, by year and exposure category.

Years		N. of blood donors°	TTI surveillance system coverage	N. of HIV Ab-positive blood donors	Exposure category			
					MSM N. (%)	Heterosexuals N. (%)	Other N. (%)	Not determined N. (%)
1999*	Total	868,391	66.3%	38	4 (10.5%)	15 (39.5%)	10 (26.3%)	9 (23.7%)
2009	Male	1,255,481		92	24 (26.1%)	32 (34.8%)	5 (5.4%)	31 (33.7%)
	Female	538,955		22	0 (0.0%)	14 (63.6%)	0 (0.0%)	8 (36.4%)
	Total	1,794,436	100.0%	114	24 (21.1%)	46 (40.4%)	5 (4.4%)	39 (34.2%)
2010	Male	1,284,881		90	23 (25.6%)	43 (47.8%)	5 (5.6%)	19 (21.0%)
	Female	555,583		14	0 (0.0%)	5 (35.7%)	2 (14.3%)	7 (50.0%)
	Total	1,840,464	100.0%	104	23 (22.1%)	48 (46.2%)	7 (6.7%)	26 (25.0%)

Legend °includes candidate donors preliminarily tested for infectious markers prior to a postponed donation; *data by gender not available; TTI: transfusion-transmissible infections.

higher than in 2009-2010 (Table II). In all 3 years, the majority of HIV antibody-positive donors reported sexual exposure as a risk factor for HIV infection and this proportion increased over time, though not significantly (Chi square for trend =0.78, P =0.38). Among HIV antibody-positive donors, heterosexuals always accounted for at least 40% of all cases, and the proportion of those who reported no determined risk factor for HIV infection was greater than 20% in all 3 years. When stratifying HIV antibody-positive donors by gender for 2009 and 2010, heterosexuals constituted the most frequent exposure category both for male and female donors (Table II). The proportions of MSM and heterosexuals increased over time; in particular, the rate of HIV antibody-positive MSM per 100,000 male donors was more than 2-fold higher in 2009-2010 than in 1999 (2009-2010 *vs* 1999, RR =2.8; P =0.06), and that of heterosexuals among all donors was 1.5-fold higher in 2009-2010 than in 1999 (2009-2010 *vs* 1999, RR = 1.5; P =0.18) (Table III). However, these differences were not statistically significant (P >0.05). When analysing only the HIV antibody-positive blood donors who reported a sexual exposure, the proportion of MSM increased over time (21.1% in 1999, 34.3% in 2009, and 32.4% in 2010; Chi square for trend =0.20; P =0.66), whereas that of heterosexuals decreased over time (78.9% in 1999, 65.7% in 2009, and 67.6% in 2010; Chi square for trend =0.07; P =0.79). Also in this case the differences were not statistically significant (test of comparison between proportions: P >0.05).

Discussion

Our results show that HIV incidence among repeat donors did not substantially change in 2009 and 2010 compared to 1999, reflecting the stable incidence of new HIV diagnoses reported at national level between 1999 and 2010[1,2], whereas HIV prevalence among first-time/lapsed donors decreased over time. However, when compared with data recently reported by other European countries[18,19], HIV incidence and prevalence reported among blood donors in Italy are higher compared to other Western European countries. This finding appears not to be attributable to a higher HIV circulation in Italy,

as shown by data reported to the ECDC[20] that indicate a similar incidence of new HIV diagnoses in the majority of Western European countries, including Italy.

The increasing proportion of HIV antibody-positive blood donors who acquired the infection through sexual contact confirms the growing proportion of newly diagnosed HIV cases attributable to sexual transmission (heterosexual and MSM contacts) in the general population at a national level. Indeed, according to data obtained from the Italian surveillance of newly diagnosed HIV infections, in 1999 MSM accounted for 16.0% and heterosexuals for 38.4% of new HIV diagnoses, whereas in 2010, MSM accounted for 40.3% and heterosexuals for 46.8% of new HIV diagnoses[1,2]. Similarly, the higher incidence and prevalence of HIV infection observed among male blood donors compared to females in 2009-2010 reflects the higher circulation of HIV among males compared to females in the general population. In Italy, since the beginning of the HIV epidemic the number of males with a newly diagnosed HIV infection has been at least twice that of females, and more than three times in several years, such as between 2005 and 2011[2].

No significant impact of the IRA policy was observed on the distribution of HIV antibody-positive donors by exposure category: in fact, both MSM and heterosexual HIV antibody-positive blood donors increased in similar proportions between 1999 and 2009-2010.

The percentage of HIV antibody-positive blood donors who reported no risk factors for HIV infection was relevant in the three studied years (for both genders in 2009 and 2010) and higher than that reported at a national level by the HIV surveillance system[2]. Given that a considerable amount of these blood donors may have acquired the infection through sexual contacts, as shown in other studies conducted among persons with AIDS[21], this result strengthens the role of unrecognised sexual risk behaviour in HIV transmission among blood donors. In Italy, data reported to the HIV surveillance system confirm the low perception of the risk of HIV acquisition through sexual contacts in that the highest proportion of "late presenters" (i.e., persons who discover that they are HIV-seropositive in an advanced

Table III - Proportion of HIV antibody (Ab)-positive first-time/lapsed and repeat blood donors, by sexual exposure: comparison of 1999 *vs* 2009 and 2010 data.

Year	MSM			Heterosexuals		
	N. of HIV Ab-positive donors per 100,000 donors	RR° (95% CI)	P	N. of HIV Ab-positive donors per 100,000 donors	RR° (95% CI)	P
1999 (reference)	0.7	1		1.7	1	
2009	1.9	2.9 (1.0-8.4)	0.06	2.6	1.5 (0.8-2.7)	0.23
2010	1.8	2.7 (0.9-7.8)	0.09	2.6	1.5 (0.8-2.7)	0.20

Legend °RR: relative risk.

stage of disease, several years after infection) is observed among newly-diagnosed HIV-positive heterosexuals[2].

When comparing the period before (1999) and after (2009-2010) the implementation of the IRA policy in 2001, no significant increase in the proportion of MSM compared to heterosexuals was observed among HIV antibody-positive blood donors, suggesting that the change in donor deferral policy has not led to a disproportionate increase of HIV-seropositive MSM. Similar findings were reported in Lombardy (a region in northern Italy with about 10 million residents), for which annual data on HIV-seropositive blood donations between 1997 and 2005 showed no significant changes in the distribution of MSM and heterosexuals among HIV-seropositive blood donors before and after the implementation of the IRA policy[22].

In all 3 years studied, at least half of the HIV antibody-positive tests were among repeat donors: this finding highlights the relevant role of this subgroup in the circulation of HIV among blood donors and deflates the belief that repeat donors are optimally informed and aware about prevention measures against transfusion-transmissible infections. Moreover, data obtained from the post-donation questionnaire suggest a low level of awareness about sexual behaviours at risk for HIV infection: of relevance, repeat donors more frequently denied having engaged in sexual risk contacts shortly prior to donation. These results show that repeat donors warrant a detailed pre-donation investigation and counselling should be as accurate as among first-time/lapsed donors. Importantly, the look-back policy for donors positive for transfusion-transmissible infections was introduced in Italy by law in 1990[23] and none of the recipients of blood products from previous donations of HIV-positive repeat donors were HIV infected. The last case of transfusion-transmitted HIV-infection in Italy was reported in 2005[24].

When considering HIV-infected donors who denied sexual behaviours at risk in the post-donation interview, we observed no differences between MSM and heterosexuals, suggesting that the attitude towards denying or not recognising sexual risk contacts in the pre-donation questionnaire and medical interview was independent of sexual orientation.

In Italy, a recent study conducted among MSM found a high prevalence of HIV (11.6%) and a high proportion of unprotected anal sex with a casual partner (43.9%) in this group[25]. Another study conducted in Italy among HIV-positive MSM showed that, even after having been diagnosed with HIV infection, a relevant proportion engaged in risk sexual contacts such as unprotected anal sex with an occasional partner (25.9%), or unprotected oral-genital sex with an occasional partner (56.6%)[26].

However, our results support the contention that the change from permanent deferral of MSM based on

sexual orientation to the IRA policy irrespective of sexual orientation has not led to an increase in the proportion of HIV antibody-positive MSM compared to heterosexuals. Although not directly comparable, a similar outcome was reported in Australia following the reduction of deferral from 5 years to 1 year for donors reporting male-with-male sex[27]. Moreover, Gallo *et al*.[28] showed that a significant proportion of blood donors, irrespective of gender and sexual orientation, consider themselves not to be at risk. Finally, Vamvakas[29] estimated that in the USA, reducing the MSM deferral from 5 years to 1 year would entail a risk of transfusion-transmitting HIV, HBV, or HCV many more than 10 times smaller than the risk from transfusing pooled platelets; in addition, the risk of introducing 1 year deferral of MSM is smaller than the currently tolerated transfusion risk that exceeds the "as low as reasonably acceptable" (ALARA) level.

The following limitations of this study need to be mentioned. The first one is the inadequate information on HIV incidence and prevalence among blood donors by exposure category before 1999 and between 2000 and 2008, which would have allowed a more accurate comparison of changes that occurred before and after the implementation of the IRA policy in 2001. The second limitation is the lacking information on the post-donation questionnaire between 2000 and 2008, which would have allowed interpretation of the changes in the awareness of blood donors about risk behaviours for acquiring sexually transmitted infections, including HIV. The large proportion (about one-quarter) of HIV antibody-positive blood donors with not determined risk factors is the third limitation, in that the correct assignment of these persons to the proper exposure category might modify the results of the distribution of risk factors. Finally, our results may not be generalised to countries with different HIV epidemics, different awareness of sexual behaviours at risk, or different procedures in blood donor selection. The face-to-face interview conducted or at least systematically supervised by a specifically trained physician in a location that guarantees privacy and confidentiality is of paramount importance to issue a reliable individual judgment of eligibility for the candidate donor.

The use of physicians to conduct individual donor risk assessment, as envisaged by Italian regulations, is not widespread although it is established in some other countries, such as France; in most countries pre-donation interviews are performed by nurses, counsellors or nursing assistants with no supervision or validation by a medical doctor. We deem that the "trust" nature of the "doctor-donor" relationship can have a significant influence on the truthfulness and reliability of the answers given by donors in the pre-donation assessment, beyond representing - in the view of the Italian regulators

and transfusion medicine community - a useful and "due" service to donors for best protection of their health. Notably, licensed physicians individually assessing blood donors' eligibility take the legal responsibility of establishing whether or not a donor is eligible case by case, under the national professional liability regulations. This is one of the reasons why Italian blood legislation, which has been in force for the last 20 years and quite recently confirmed, assumes that an accurate and reliable selection of blood donors can be guaranteed only by suitably trained physicians, given its potential impact on blood safety and relevant legal implications.

Conclusions

In conclusion, our results show that the implementation of the IRA policy in 2001 did not significantly affect either the incidence or prevalence of HIV infection among blood donors or the distribution of MSM and heterosexuals among HIV antibody-positive blood donors. Before and after 2001, unprotected heterosexual contacts represented the main route of HIV acquisition not only among blood donors but also in the general population at a national level. The higher incidence and prevalence of HIV observed among blood donors in Italy compared to other Western European countries suggest an inadequate level of awareness of risk behaviours, especially among repeat blood donors, rather than a greater spread of HIV infection. Importantly, this is shown to be a common occurrence in the general population rather than a specific characteristic of blood donors. The low perception of the risk of acquiring HIV infection through sexual contact appears to be relevant in both heterosexuals and MSM, stressing the need for clearer, more explicit and homogeneous educational material on sexual risk behaviour to be offered nationwide to blood donors prior to donation, together with a standardised pre-donation questionnaire. Moreover, it is very important to standardise and systematically apply the post-donation interview so as to appropriately investigate at-risk factors occurring in confirmed HIV-positive blood donors; as a consequence, more detailed and reliable epidemiological data on the HIV epidemic among blood donors could be obtained, which should be used to provide further evidence on the relationship between specific risk behaviours (such as MSM contacts at risk) and blood safety.

The Authors declare no conflicts of interest.

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