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Acceptability of HIV Vaccine - Efficacy Trials in Drug Users and Sexual Partners of HIV Infected Patients in Barcelona, Spain

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1. Introduction

The epidemiology of HIV infection in Spain has changed during the past decade. Surveillance of HIV infection occurs in 15 of the country's 17 regions, and 2,264 new HIV infections were diagnosed in 2009 (Ministerio de Sanidad y Política Social, Ministerio de Ciencia e Innovación, 2010).

As previously reported (Hernandez-Aguado, 1999), the HIV epidemic in Spain has been largely driven by injecting drug users (IDUs). Reductions in the rates of new infections among drug users were reported a decade ago for the first time since the beginning of the epidemic (Castilla, 2006). In 2009, 77.0% of new infections were acquired through sexual transmission, and IDUs represented less than 10% of reported cases (Ministerio de Sanidad y Política Social, Ministerio de Ciencia e Innovación, 2010).

The HIV epidemic among IDUs continues to develop heterogeneously across different parts of Europe. In the European Union, the reported rates of newly diagnosed cases of HIV infection in IDUs are mostly stable or in decline (European Monitoring Centre for Drugs and Drug Addiction, 2009). Data on newly reported cases of HIV infection in IDUs for 2007 suggest that rates of infection are still declining in Europe following a peak in 2002, which was caused by outbreaks in Estonia, Latvia and Lithuania. In 2007, the overall rate of newly reported infections of HIV among IDUs in the 24 EU member states for which national data

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were available was 4.7 cases per million population, slightly lower than the 5.0 per million population reported in 2006.

Non-injecting drug users are not parenterally exposed to HIV infection, but they remain at risk of acquiring HIV through sexual transmission. Several studies regarding risky sexual practices suggest an association between the abuse of cocaine, amphetamines, and alcohol and sexual transmission of HIV (Wang, 2010; Baliunas, 2010; Booth, 2000; de Azevedo, 2007; Colfax, 2010; Van Tieu, 2009). For these reasons, it is clear that drug users, independent of the route of administration, are a population at risk of HIV infection. Therefore, they are candidates for participation in studies on the efficacy of a preventive vaccine.

In Spain in 2009, the most prevalent route of acquisition of HIV was through transmission among men who have sex with men (MSM) (42.5%), followed by heterosexual transmission, who represented 34.5% of cases. Among men, over 50% of new HIV diagnoses are associated with MSM transmission. There has been a downward trend in the proportion of cases from heterosexual transmission (44.4% of cases in 2004 and 34.5% of cases in 2009). In contrast, MSM transmission accounts for a growing proportion of cases, increasing from 28.8% in 2004 to 42.5% in 2009 (Ministerio de Sanidad y Política Social, Ministerio de Ciencia e Innovación, 2010). Several risk factors contribute to the sexual transmission of HIV, including socioeconomic status and individual factors such as having multiple sexual partners or unprotected sex (Staras, 2009; Hallfors, 2007; Adimora, 2006).

The development of effective vaccines against HIV is the main focus of HIV research and provides hope for limiting the epidemic. In phase III clinical trials of a vaccine, the involvement of thousands of people and a measure of the background incidence of HIV infection are necessary to establish population efficacy (Celentano, 1995; Vanichseni, 2001; Newman, 2010b). Cohorts with less than 2 × 100 person-years (p-y) of HIV incidence and less than 90% retention are considered inappropriate for these trials partly because they are not likely to provide sufficient statistical power to demonstrate an effect of the intervention. The HIV incidence rate in a vaccine efficacy trial performed among IDUs from Thailand showed an HIV incidence rate of 3.4 per 100 p-y (Suntharasamai, 2009); in IDUs from metropolitan Barcelona, incidence is half that shown in the vaccine efficacy trial performed in Thailand in the same type of population (Muga, 2010). In other studies, the rate has varied by geographic area (Kozlov, 2006; Kellogg, 2001; Bruandet, 2006; Duan, 2009).

Globally, cohorts of HIV-negative individuals at high risk of HIV infection have been extensively studied to monitor the incidence of HIV-1 and assess their involvement in vaccine efficacy studies. Currently, there are three international phase III HIV vaccine studies (Table 1). Spain participates in an increasing number of European and North American initiatives to prepare for preventive HIV vaccine trials, but few studies have evaluated the acceptability of a preventive vaccine against HIV/AIDS among potential recipients and their willingness to participate in clinical trials (Etcheverry, 2011).

Factors positively correlated with a decision to participate in a HIV vaccine trial may include altruism, higher education level, suspected exposure to HIV, protection against HIV infection, and free medical care and economic incentives (Strauss, 2001; Golub, 2005). Barriers to participation include little information about the vaccine trials, vaccine-induced seropositivity to HIV in tests, and associated stigma or discrimination (Strauss, 2001; Golub, 2005). Given the historical underutilization of existing preventive vaccines, such as the

hepatitis B vaccine, among MSM (in part due to a lack of information (Jacobson, 2007; Schutten, 2002)), it is important to anticipate and understand the characteristics of potential volunteers for an HIV vaccine trial in detail.

Trial ID	Strategy	Group of risk	Start Date	Volunteers
RV 144	Viral vector-Pox/Protein	HIV-uninfected Thai adults	10/2/2003	16,403
VAX 003	Protein	Intravenous drug users in Bangkok	3/1/1999	2,500
VAX 004	Protein	Adults at risk of sexually transmitted HIV in North America	6/1/1998	5,400

Table 1. Characteristics of current phase III clinical trials. Information was taken from the Database of AIDS Vaccine Candidates in Clinical Trials available at http://www.iavireport.org.

The main objective of this study was to assess HIV risk behavior in drug users and sexual partners of HIV-infected patients and to analyze the degree of acceptance and willingness to participate (WTP) in HIV vaccine efficacy trials in metropolitan Barcelona.

2. Patients and methods

Drug addicts were recruited in two centers for substance abuse treatment located in Badalona, Spain (Hospital Universitari Germans Trias i Pujol and the Municipal Center for Substance Abuse Treatment, known as CAS Delta) between November 2007 and May 2010. During the same period, sexual partners of HIV-infected patients were recruited in an HIV/AIDS unit at the Hospital Universitari Germans Trias i Pujol.

The three patient enrollment sites in the study were located in Badalona, north of Barcelona. The CAS Delta treats patients with substance abuse who live in two cities, Badalona (220,000 inhabitants) and Santa Coloma de Gramenet (110,000 inhabitants). The Hospital Universitari Germans Trias i Pujol is a tertiary teaching hospital with 600 beds in Badalona; the HIV/AIDS Unit at Hospital Universitari Germans Trias i Pujol treated in 2010 more than 1,500 HIV-positive patients.

Drug users were diagnosed with drug dependence disorders according to the Diagnostic and Statistical Manual of Mental Disorders, 4th ed. (DSM-IV) (American Psychiatric Association, 2000) and had been referred for substance abuse treatment. The primary drugs of abuse were stimulants (cocaine) and depressants (opiates and alcohol). To be considered for inclusion in the study, drug users had to 1) be 18 years of age or older, 2) be actively using drugs, 3) have HIV-negative status at the time of inclusion, and 4) give informed consent. Drug users at risk of infection who met the inclusion criteria answered a 56-question survey, which collected data on personal history (age, sex, place of origin, educational level, and employment status), drug use (the quantity, frequency, and treatment history for alcohol, cocaine, heroin, and other substances), sexual behavior (sexual orientation, number of partners, characteristics of the sexual partners regarding drug use

and paid sex, and condom use), history of sexually transmitted diseases, knowledge and opinions about a potential HIV vaccine, WTP, and the subject's availability for an extended follow up. The survey questions were presented by doctors and nurses from both recruiting centers, individually and in a quiet setting with no other people present.

To be considered for inclusion in the study, sexual partners of patients with HIV infection had to 1) be 18 years old or older, 2) have been a stable partner for at least 6 months, 3) be HIV-negative at the time of inclusion, and 4) give informed consent. Participants were given a shortened version of the previously described questionnaire that collected data on personal history, sexual behavior, and WTP. The questionnaire was given in the HIV/AIDS unit and was conducted by trained personnel.

In both groups at risk for HIV infection, the degree of WTP in a potential HIV vaccine-efficacy trial was assessed on a four-point scale questionnaire:

a. I am definitely willing to participate [definitely yes];
b. I want to participate, but need to think about it [probably yes];
c. I do not want to participate but will think about it [probably not];
d. I am not at all willing to participate [definitely not].

The group of drug users was given an additional question related to the possibility of receiving remuneration for participating in a vaccine study: If you were paid, would you agree to volunteer in a potential HIV vaccine efficacy trial?

After the questionnaires were completed, participants were scheduled for a blood draw to detect possible HIV, hepatitis C virus (HCV), and hepatitis B virus (HBV) infections. The blood samples were tested by enzyme immunoassay (EIA) for antibodies to HIV infection (Genetic Systems, Bio-Rad Laboratories, Seattle, WA or Abbot HIVAB, Abbot Laboratories, North Chicago, IL) and confirmed by western blot. Infection with HCV was determined by EIA (Ortho HCV, Ortho Diagnostics, Raritan, NJ). Blood samples were tested for the HBV surface antigen (Auszyme Monoclonal EIA or AxSYM microparticle enzyme immunoassay (MEIA), Abbott Laboratories, North Chicago, IL), anti-HBs (Ausab (EIA) or AxSYM (MEIA), Abbot Laboratories, North Chicago, IL), and anti-HBc (Corzyme (EIA) or AxSYM (MEIA), Abbot Laboratories, North Chicago, IL).

The methods used to conduct this study met the ethical standards for medical research and the principles of good clinical practice.

2.1 Statistical analysis

Data from the two groups at risk of HIV infection were pooled. A total of 21 variables were common to both risk groups.

For drug users, we developed an index that evaluated the level of risk of infection based on 10 questions:

1. Have you ever used drugs intravenously?
2. Have you shared elements to inject?
3. How many sexual partners have you had in the past year?
4. Have you had sex for drugs?
5. Have you ever had sex with people who were under the influence of drugs?
6. Have you ever had sex with prostitutes?
7. Have you ever had sex with someone infected with HIV?
8. Have you had sex under the influence of drugs?

9. When you have a steady partner, do you use condoms?
10. When you do not have a steady partner, do use condoms?

For each of the questions, we created an indicator, 0/1, corresponding to no risk/risk. We then summed the indicators obtained for all ten questions. A value between 0 and 3 points was defined as low risk, between 4 and 6 points as moderate risk, and more than 6 points as high risk.

We performed a descriptive analysis and a bivariate analysis by risk group for HIV infection, WTP, and other variables of interest. The outcome variable of WTP was dichotomized so that there were enough subjects in each category for comparison: the variable was "yes" if WTP was "definitely willing" or "probably willing" and "no" if the answer was "probably not" or "definitely not".

We used the chi-square test, Fisher's F-test, and Student's t-test when appropriate to detect significant differences. In addition, we calculated the odds ratio to quantify the probabilities of WTP. Logistic regression methods were used to determine predictive factors for participation in a phase III clinical trial. Variables that were statistically significant in the bivariate analysis were used as co-variables in the regression. Data were entered into a Microsoft Access 2003 database. All statistical analyses were performed using Stata software (version 8.0; StataCorp, College Station, TX). Values of $p < 0.05$ were considered statistically significant.

3. Results

A total of 232 HIV-seronegative individuals were analyzed. The median age at study entry was 39 years (interquartile range (IQR), 33-45 years), and 64% were men. Almost 17% of participants had attained at least a high school education. Seventy-nine individuals (34%) were drug users, and 153 (66%) were sexual partners of HIV-positive patients. Among drug users, 82.3% were men, the median age was 35.4 years (IQR, 29.4 - 40.0 years), most (57.7%) had finished elementary school, and 96.2% were heterosexual. Among the sexual partners, 54.2% were men, the median age was 41 years (IQR, 35.6 - 46.6), 40% had completed middle school, and 67.5% were heterosexual. These and other results can be seen in Table 2, which summarizes the characteristics of the study population overall and by risk group.

The overall prevalence of HCV was 20.5%. This prevalence was higher among drug users than in the other group (41.6% vs. 8.3%). Among drug users, 22.4% (11/49) had a serologic pattern of HBV-vaccine-induced immunity [i.e., HBsAg (-), HBsAb (+), and HBcAb (-)], and the serology of 7 of 49 (14.3%) users reflected immunity from natural infection.

None of the sexual partners of the HIV-positive patients had the three serological markers of HBV. In the same blood sample, we confirmed that all participants were negative for HIV. Table 3 summarizes the HCV and HBV statuses of participants at the time of inclusion in the study.

With regard to risky behaviors of drug users, it was noted that 46% (36/78) were or had been IDUs, and 50% admitted to having shared injecting equipment at some point. In addition, 45% of IDUs reported that they drank alcohol daily, 35.5% had been to jail, and 14.7% had never used condoms despite not having had a stable sexual partner. In general, the level of risk of HIV infection was low for approximately 55% of drug users (43/78) and elevated in 7.7% (6/78). These and related findings on risky behavior among drug users are summarized in Table 4.

	Drug users N = 79 n (%)	Sexual partners of HIV+ patients N = 153 n (%)	Total N = 232 n (%)
Gender			
Male	65 (82.3)	83 (54.2)	148 (63.8)
Female	14 (17.7)	70 (45.8)	84 (36.2)
Age (median [IQR])	35.4 [29.4-40.0]	41.1 [35.6-46.6]	39.3 [33.0-44.8]
Education (n=128)			
None	8 (10.3)	2 (1.4)	10 (4.4)
Primary school	45 (57.7)	50 (34.0)	95 (42.2)
Middle school	23 (29.5)	59 (40.1)	82 (36.4)
High school	2 (2.5)	36 (24.5)	38 (16.9)
Last consumption of drugs (n=231)			
Never	0 (0)	123 (80.4)	123 (53.2)
< 1 month	54 (69.2)	25 (16.3)	79 (34.2)
1-12 months	19 (24.4)	2 (1.3)	21 (9.1)
> 12 months	5 (6.4)	3 (2.0)	8 (3.5)
Sexual behavior (n=128)			
Homosexual	1 (1.3)	49 (32.5)	50 (21.8)
Heterosexual	75 (96.2)	102 (67.5)	177 (77.3)
Bisexual	2 (2.6)	0 (0.0)	2 (0.9)
Willingness to participate			
No	48 (60.7)	1 (0.7)	49 (21.1)
Yes	31 (39.3)	152 (99.3)	183 (78.9)

Table 2. Characteristics of drug users and HIV-positive sexual partners.

	Drug users n / N (%)	Sexual partner of HIV+ patients n / N (%)	Total n / N (%)
HCV+	32/77 (41.6)	11/133 (8.3)	43/210 (20.5)
HBsAg+	0/72 (0)	1/77 (1.3)	1/149 (0.7)
HBcAb+	13/62 (21.0)	11/42 (26.2)	24/104 (23.1)
HBsAb+	19/52 (36.5)	16/42 (38.1)	35/94 (37.2)

Table 3. Serological status of the study population according to risk of infection.

	N=79 n (%)
Recent (< 1 year) usage of IV drugs (n=78)	14 (17.9)
History (> 1 year) of IV drug use (n=78)	22 (28.2)
Have you shared injecting equipment? (n=36)	
Yes	18 (50.0)
No	18 (50.0)
Do you go to the needle-exchange locations? (n=32)	
Yes	14 (43.7)
No	18 (56.3)
Are you in a methadone program? (n=77)	
Yes	29 (37.7)
No	48 (62.3)
Have you consumed alcohol in the past year? (n=78)	
Yes	47 (60.3)
No	31 (39.7)
Do you consume alcohol daily? (n=47)	
Yes	22 (46.8)
No	25 (53.2)
Have you required medical attention for drug use in the past year? (n=74)	
Yes	26 (35.1)
No	48 (64.9)
Have you been in prison? (n=76)	
Yes	27 (35.5)
No	49 (64.5)
How many sexual partners have you had in the past year? (n=78)	
0	17 (21.8)
1-5	55 (70.5)
6-10	3 (3.8)
11-20	1 (1.3)
>20	2 (2.6)
Have you had sex for drugs? (n=78)	
Yes	4 (5.1)
No	73 (93.6)
Don't know/refused	1 (1.3)

Table 4. Risk behaviors in drug users at risk of HIV infection.

	N=79 n (%)
Have you had sex with people who were under the influence of drugs? (n=78)	
Yes	51 (65.4)
No	26 (33.3)
Don't know/refused	1 (1.3)
Have you had sex with prostitutes? (n=74)	
Yes	40 (54.0)
No	33 (44.6)
Don't know/refused	1 (1.4)
Have you had sex with someone infected with HIV? (n=78)	
Yes	9 (11.5)
No	60 (76.9)
Don't know/refused	9 (11.6)
Have you had sex while under the influence of drugs? (n=78)	
Yes	68 (87.2)
No	10 (12.8)
Don't know/refused	0 (0)
Do you currently have a steady partner? (n=78)	
Yes	34 (43.6)
No	44 (56.4)
When you have a steady partner, do you use condoms? (n=76)	
Always	14 (18.4)
Sometimes	27 (35.5)
Never	35 (46.1)
When you have no steady partner, do you use condoms? (n=75)	
Always	43 (57.3)
Sometimes	21 (28.0)
Never	11 (14.7)

Table 4. (Cont.). Risk behaviors in drug users at risk of HIV infection.

Notably, nearly 30% of the stable partners of HIV-infected people did not consistently use condoms, and 23.2% acknowledged having had sex under the influence of drugs. Table 5 summarizes risk behaviors in this population.

Overall, 47.4% of participants answered that they would definitely be willing to participate in HIV vaccine efficacy trials, 31.5% were probably willing, 9.1% wrote they were probably not willing, and 12.1% indicated they were definitely not willing to join vaccine trials. Among drug addicts, 13.9% were definitely willing to participate, in contrast to 64.7% of sexual partners of HIV-infected patients ($p<0.05$). Figure 1 shows the characteristics of WTP according to both study populations. Among drug users, it should be noted that only one person indicated a shift in WTP from "probably no" to "probably yes" if the study were to involve remuneration.

	N=153 n (%)
Have you used drugs in the past month?	
Yes	30 (19.6)
No	123 (80.4)
Do you have a history of IV drug use?	3 (2.0)
Have you had sex with people under the influence of drugs? (n=56)	
Yes	13 (23.2)
No	42 (75.0)
Don't know/refused	1 (1.8)
Have you had sex with prostitutes? (n=67)	
Yes	14 (20.9)
No	52 (77.6)
Don't know/refused	1 (1.5)
Have you had sex while under the influence of drugs? (n=150)	
Yes	16 (10.7)
No	134 (89.3)
When you have a steady partner, do you use condoms? (n=146)	
Always	104 (71.2)
Sometimes	29 (19.9)
Never	13 (8.9)

Table 5. Sexual risk behaviors of sexual partners of HIV-infected patients.

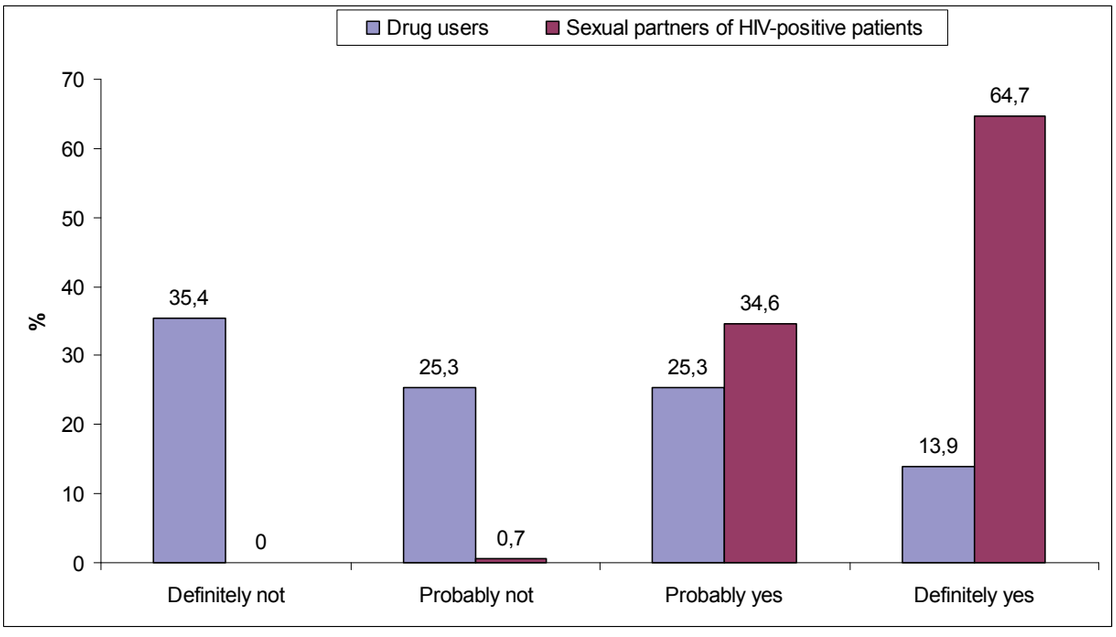


Fig. 1. Willingness to participate in HIV vaccine efficacy trials among drug addicts and sexual partners of HIV-positive patients in Badalona, Spain.

Table 6 summarizes WTP in both risk groups. This table shows that WTP in drug users is more common in women, in those with elementary-school education, in those who have recently used drugs, and in those who show a high number of risk behaviors. In sexual partners of HIV-positive patients, the vast majority (>95%) would be willing to participate in a clinical trial.

	Willingness to participate			
	Drug users N=79		**Sexual partners of HIV-positive patients N=153**	
	n (%)	p-value	n (%)	p-value
Gender				
Male	22 (33.8)	0.034	83 (100.0)	0.458*
Female	9 (64.3)		69 (98.6)	
Age (mean ± SD)	34.9 ± 9.5	0.944	41.6 ± 8.3	0.872
Education (n=128)				
None	3 (37.5)	0.647	2 (100.0)	1.000*
Elementary school	19 (42.2)		50 (100.0)	
Middle	8 (34.8)		58 (98.3)	
High	0 (0)		36 (100.0)	
Last consumption of drugs (n=231)				
Never	--	0.588	122 (99.2)	1.000*
< 1 month	23 (42.6)		25 (100.0)	
1-12 months	7 (36.8)		2 (100.0)	
> 12 months	1 (20.0)		3 (100.0)	
Sexual behavior (n=128)				
Homosexual	1 (100.0)	0.059*	101 (99.0)	1.000*
Heterosexual	28 (37.3)		49 (100.0)	
Bisexual	2 (100.0)		--	
Risk behavior				
Low	10 (23.8)	0.003		
Moderate	16 (55.3)			
High	5 (83.3)			

* F-test

Table 6. Willingness to participate in HIV vaccine trials among drug users and sexual partners of HIV-positive patients.

There were also significant differences between drug users by gender. The probability that a female drug user agreed to participate in a future vaccine trial for HIV was more than three times higher than in men (OR = 3.52, 95% CI: 1.05-11.77). Having a moderate or high risk of HIV infection (> 3 points) was also associated with WTP (OR = 4.48, 95% CI: 1.70-11.83). Figure 2 shows WTP according to the level of risk of HIV infection in drug users.

In the multivariate analysis, being female (OR = 5.6, 95% CI: 1.4-22.4) and having a moderate-to-high level of infection risk (OR = 6.6, 95% CI: 2.2-19.6) were predictors of participation in a phase III vaccine trial among drug users.

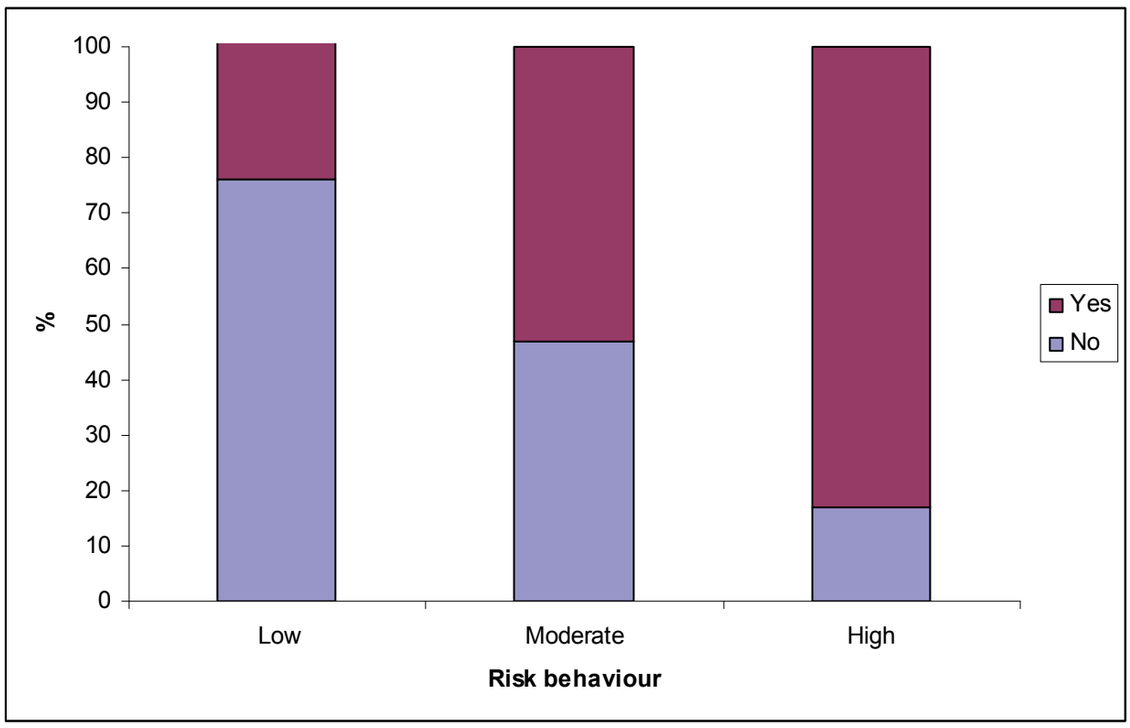


Fig. 2. Willingness to participate according to the level of risk of HIV infection in drug users.

4. Conclusion

Understanding the candidate population of volunteers is crucial for analyzing the efficacy of a potential preventive vaccine trial. In Spain, drug users have exhibited an elevated risk of HIV infection. In anticipation of a safe and effective vaccine candidate, it is appropriate to assess potential sites and populations for future vaccine trials. Accordingly, this study was developed to analyze WTP in a hypothetical HIV vaccine efficacy trial among current drug users in an urban area, many of whom have been affected by HIV/AIDS and parenteral drug addiction for many years. Sexual partners of HIV-infected patients are, by definition, another population at risk and therefore also potential trial participants.

In this study, we observed that WTP is clearly higher in sexual partners of HIV-positive patients and falls far short of 40% in potentially eligible drug users. To the best of our knowledge, this is the first study to report WTP in HIV vaccine trials in sexual partners of HIV patients in Spain. A high rate of acceptability of an HIV vaccine trial in this risk group has not been reported in other countries, although one study has demonstrated WTP in an overwhelming majority of monogamous married women (Suhadev, 2006). A predisposition toward WTP is already known among homosexuals (Newman, 2010b; Li, 2010) and, more particularly, in those who report family support for participation and expect that the vaccine will protect them against HIV infection (Li, 2010).

The WTP of drug users in this study was lower than that of other studies conducted in our area and in other areas. For example, a study recently conducted in our area on 326 drug users found WTP in 83% of cases (51% would definitely participate, and 32% would probably participate) (Etcheverry, 2011). In China, a study conducted among 401 IDUs

showed a rate of definite WTP of approximately 75%; the rate reached 94% if the group that indicated a probable WTP was included (Yin, 2008).

One of the findings among drug users is noteworthy: those who showed an increased risk of infection were the most likely to agree to participate in a phase III vaccine trial. A recent meta-analysis of HIV vaccine acceptability indicated a significant impact of self-identification as a member of a risk group and perceived susceptibility to HIV infection on HIV vaccine acceptability, thus suggesting potentially modifiable factors beyond vaccine characteristics that may influence uptake (Newman, 2010a). This finding may explain the high rate of WTP in this subgroup of drug users compared to the mean of this population (83.3% vs. 39.2%).

Among active drug users, women showed greater willingness to participate in a phase III vaccine trial. Greater availability and motivation of women has also been noted in other studies, although in different risk groups (Aliyu, 2010; Colfax, 2005).

The rate of HIV incidence among IDUs in our area is half that found in a similar population in Thailand (Suntharasamai, 2009; Muga, 2010). In the study by Muga et al., the proportion of IDUs admitted for substance abuse treatment had decreased considerably in recent years (Muga, 2010). When combined with the relatively low incidence of HIV infection in recently recruited IDUs, these data suggest that drug users may not be included in future studies on preventive HIV/AIDS vaccine efficacy trials.

The results from this study indicate that the prevalence of HCV in drug users and in sexual partners of HIV-positive patients is relatively high (41.6% and 8.3%, respectively). These results suggest the possibility that some of the individuals in the drug users group who self-reported as non-IDUs may have injected drugs in the past. However, the risk of sexual transmission of an HCV infection is associated with a history of multiple sexual partners and a lack of condom usage (Alter, 1990; Osmond, 1993; Rauch, 2005). Thus, the high prevalence of HCV infection in both risk groups in this study could be explained by the large number of subjects who said that they never use condoms. It was also noted that over 20% of drug users had been vaccinated for HBV. Although the percentage of people vaccinated against HBV is low globally, these results are consistent with others noting that vaccine-induced immunity to HBV infection in Spain has been increasing (Rivas, 2010).

Several limitations of this study should be mentioned. First, the survey did not include issues related to vaccine trial attributes, such as vaccine-induced infection, side effects, or false-positives on HIV tests, which are associated with lower WTP (Mills, 2004). Thus, the results of this study may overestimate WTP. In addition, self-reported data on risk behaviors related to drug use and sexual behavior could overestimate current risk behaviors. This study has a cross-sectional design and therefore cannot analyze changes in the WTP that might be seen following retention strategies and vaccine education.

This is the first study in Spain to evaluate WTP among sexual partners of HIV-positive patients. The number of people at risk who participated is high, and the study environment is appropriate because the involved facilities have the ability to implement phase I or II vaccine trials.

In the case of a phase III preventive vaccine trial in Spain, it could become necessary to recruit a large number of people at risk of infection. The stated WTP in hypothetical HIV vaccine trials was high among sexual partners of HIV-positive patients. Specific interventions are needed to increase the acceptability of vaccine trial participation among drug users at risk of HIV infection.

Recommended Sites of HIV/AIDS Vaccine Initiatives
Internacional AIDS Vaccine Initiative: http://www.iavi.org
HIV Vaccine Trials Network: http://www.hvtn.org
World Health Organization: http://www.who.int/hiv/topics/vaccines/Vaccines
AIDS Vaccine Advocacy Coalition: http://www.avac.org
Vaccine Research Center: http://www.niaid.nih.gov/about/organization/vrc

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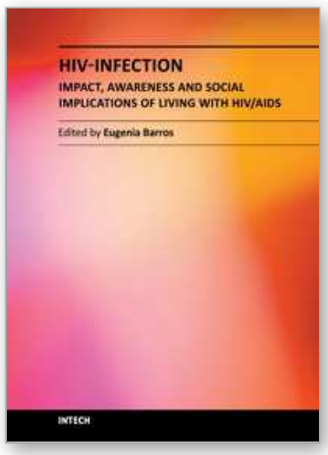
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The past few decades have seen the escalation of HIV-infections and the 'frantic' search for new drugs to treat the millions of people that live with HIV-AIDS. However because HIV-AIDS cannot be cured, but only controlled with drugs, and the Antiretroviral (ARV) treatment itself results in some undesirable conditions, it is important to generate wider awareness of the plight of people living with this condition. This book attempts to provide information of the initiatives that have been used, successfully or unsuccessfully, to both prevent and combat this 'pandemic' taking into consideration the social, economic, cultural and educational aspects that involve individuals, communities and the countries affected.

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