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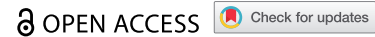


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BRIEF REPORT



Determinants of non-compliance with additional booster doses of the SARS-CoV-2 vaccine in people living with HIV (PWH): An observational study based on a behavioral and epidemiological survey in Rome (Italy)

Giulia Del Duca^a, Isabella Sperduti^b, Alessandro Cozzi Lepri^c, Valentina Mazzotta^a, Francis Drobniewski^d, Roberta Gagliardini^a, Marisa Fusto^a, Maria Maddalena Plazzi^a, Jessica Paulicelli^a, Alessandra Vergori^a, Chiara De Ponte^e, Paolo Faccendini^e, Paola Galli^f, Enrico Girardi^g, and Andrea Antinori^a

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ABSTRACT

Rejection of new anti-SARS-CoV-2 booster doses among immunosuppressed and elderly individuals may be a concern, especially as the intention to vaccinate does not always translate into actual behavior. Few studies have addressed this issue in people living with HIV (PWH). We investigated attitudes of PWH toward SARS-CoV-2 vaccination, focusing on factors associated with noncompliance with additional vaccine doses (AVDs, 4th and 5th). We analyzed participants of the prospective observational HIV-VAC study conducted at the National Institute for Infectious Diseases “L. Spallanzani” IRCCS, Rome (September 2022–June 2023). Eligible patients with complete vaccination schedules were voluntarily recruited and completed a 13-item survey on demographics and vaccination attitudes. Multivariate logistic regression was used to describe the relationship between “compliant” vs. “non-compliant” groups. Of 316 participants, 240 (75.9%) were compliant and 76 (24.1%) non-compliant. Compliance was 70% for the fourth and 30% for the fifth dose; noncompliance was 19.9% and 4.1%, respectively. Older age ($p = .012$) and information from non-institutional sources ($p < .0001$) were associated with higher noncompliance. Among non-compliant participants, 34.4% reported concerns about side effects. In PWH aged >50 , fear of side effects and reliance on unofficial information sources are major barriers to AVD uptake. Non-compliant individuals tend to persist in their refusal over time. Tailored communication and healthcare professional training are crucial to improve vaccine adherence, and further multicenter studies are warranted.

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COVID-19 infection; COVID-19 vaccination; booster doses; vaccine acceptance; vaccine hesitancy; actual behavior

Introduction

Background and purpose

The global health emergency due to the COVID-19 pandemic has ended, and we now find ourselves in a context of stabilized disease with which we will probably live for many years to come. While the overall severity of COVID-19 has decreased, it is crucial to remember that certain populations remain at higher risk for severe outcomes, including immunocompromised subjects to which people living with HIV (PWH) belong.

In its HIV surveillance report, the WHO recorded a total of 112,883 new HIV diagnoses in 47 of the 53 countries in 2023, of which 24,731 were reported by the 30 countries of the European Union/European Economic Area (EU/EEA).¹ Specifically in Italy, approximately 2,300 new cases were recorded in 2023, with an HIV prevalence of approximately 140,000 cases and an 11.8% increase rate between 2022 and 2023,

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attributable to factors such as a resumption of HIV testing and case detection after the COVID-19 pandemic.²

These populations require continued vigilance and specific measures to protect them from severe COVID-19, such as vaccination against SARS-CoV-2.³ While COVID-19 vaccination is generally effective in preventing severe illness and death,⁴ its efficacy may be somewhat reduced in PWH. This necessitates tailored vaccination strategies and potential considerations for additional/booster doses.⁵

To date, data available on the immunogenicity of mRNA vaccines in PWH have shown satisfactory humoral responses, particularly in those with a CD4 count $\geq 500/\text{mm}^3$ at the time of vaccination, with humoral response rates comparable to those in the HIV-negative population.⁶ There is also evidence to support a difference in humoral response to the third dose depending on the type of vaccine sequence received.^{7,8}

On 17 September 2024, the Ministry of Health published the Circular No. 27825, based on recent scientific evidence from the WHO, EMA, ECDC and AIFA, providing guidance and recommendations for the administration of the updated vaccine (Comirnaty Omicron XBB 1.5 Pfizer; Nuvaxovid XBB 1.5 Novavax3) to be used for both the booster and the first dose. One dose of vaccine (annual booster) is actively offered to PWH with acquired immunodeficiency syndrome (AIDS), or with a CD4+ T-cell count < 200 cells/ μL , or on the basis of clinical judgment. The booster is normally effective for 12 months and a single dose of the adapted vaccine is also recommended for those who have never been vaccinated (primary cycle). Having contracted SARS-CoV-2 infection, even recently after the previous booster, is not a contraindication to vaccination. The distance in time between the most recent COVID-19 vaccine dose and the booster must be at least three months.^{9,10}

Vaccination hesitancy is known to be a widespread problem in the general population, being defined as one of the top 10 threats to global health in terms of vaccination refusal or delayed acceptance.^{11–13}

Although the efficacy and safety of many vaccines, such as SARS-CoV-2 vaccine, have been well established, many people consider vaccines useless and doubt their efficacy and safety.¹⁴ In Italy, during the COVID-19 pandemic, reluctance to receive vaccines has increased, with almost one in five people expressing mistrust and fear toward vaccines and the scientific community.^{15–17} Many reasons can cause hesitation about COVID-19 vaccination, including fear of side effects, the spread of false information and news, religious beliefs, and political ideology.¹⁸ Some studies have focused on the cognitive variables of acceptance and hesitation, including vaccine confidence and complacency,¹⁹ general self-efficacy and specific self-efficacy in preventing COVID-19,²⁰ and locus of control. In order to develop a response comparable to that of non-infected persons, for whom the vaccination schedule calls for only one seasonal booster dose (once a year) if they fall into risk categories (age ≥ 60 years, chronic diseases, pregnancy, healthcare workers), while for the rest of the healthy population the booster is optional and not offered systematically every year, PWH require additional vaccine doses compared to the primary cycle. Therefore, noncompliance with the recommended vaccination schedule among PWH with uncontrolled HIV infection or advanced immunodeficiency, or in the context of additional comorbidities such as obesity, diabetes, respiratory, cardiovascular, renal or hepatic diseases, and the consequent refusal of additional doses of the SARS-CoV-2 vaccine (AVDs), may expose them to a greater risk of severe COVID-19 and/or death. In addition, the emergence of SARS-CoV-2 variants could result from more intense and prolonged viral replication in immunocompromised individuals such as certain categories of patients with HIV-1 infection, favoring the accumulation of other mutations and thus an evolutionary advantage, as well as a more rapid spread of SARS-CoV-2.²¹ International guidelines strongly support the principle that PWH may need more frequent boosters or additional doses in the long term, as long as COVID-19 remains a circulating virus that is dangerous for immunocompromised individuals.

Often, however, the intention to vaccinate does not correspond to actual vaccination. This has meant that to date, most studies have focused more on the issues of intention and acceptance of vaccines rather than their actual uptake.¹³ Therefore, here we aim to investigate attitudes toward the SARS-CoV-2 vaccine by analyzing the empirical factors associated with noncompliance and actual behavior to receive AVDs (fourth and fifth doses).

Methods

Study design, data collection methods and sample characteristics

The protocol of the HIV-VAC Study, prospective observational, single-center study was conducted at the Viral Immunodeficiency Unit, a reference center of the National Institute for Infectious Diseases 'L.

Spallanzani' IRCCS in Rome(Italy) a unit dedicated to the outpatient care of patients with HIV infection and related complications, with a clinical trial center for HIV/AIDS aimed at managing clinical trials on antiretroviral drugs, vaccination programs and other aspects related to the disease (co-infections, noninfectious comorbidities). COVID-19 vaccination is offered as part of routine care for all patients attending the clinic, although each patient has the option of receiving vaccinations at a different location, in which case they are required to disclose their PWH status. PWH, or with CD4+ T-cell counts <200 cells/ μ l or based on clinical judgment (>18 years) were therefore enrolled, through voluntary recruitment, during their outpatient visit with the infectious disease specialist. Conversely, the following conditions represented exclusion criteria: 1) inability or refusal to sign informed consent, 2) exclusion from vaccination due to clinical contraindications and 3) lack of basic knowledge of the Italian language.

Data presented in the following manuscript refer to recruitment conducted between September 2022 and June 2023, period during which the fourth and fifth doses of the SARS-CoV-2 vaccine were offered at our center.

Patients are divided into two groups: those who reported adhering to the ADV are defined as compliant, while those who reported no adherence, are defined as non-compliant. These definitions were developed specifically for the population covered by our study based on a review of the available reference literature. Furthermore, in order to verify how many of them had actually complied with their intentions or not, we checked for the presence or absence of adherence to the AVDs within our database updated in February 2024. All information regarding clinical, demographic and behavioral data was acquired via an electronic case report form (eCRF). Participants were identified exclusively by numeric codes and their protection is ensured through the use of passwords.

Survey administration

A paper-based survey, consisting of 13 multiple-choice items, was developed by a team of neuropsychologists, specialists in infectious diseases and epidemiology to conduct the behavioral survey at the Viral Immunodeficiency Unit.

The survey was proposed by neuropsychologists and/or infectious disease specialists to all patients who came to the clinic at the end of their checkups. Once accepted, participants self-administered the survey in the clinician's office. It took about 20 min to complete. No participants received compensation for their time.

The survey was administered one single time, during the outpatient visit; it is divided into three sections: "*sociodemographic information*" section, "*sources of information*" section and "*propensity, attitude and concerns regarding new SARS-CoV-2 vaccine doses*" section.

The questions were structured in line with the reference literature for the identification of *contextual determinants*, such as historical, social and cultural factors that may influence vaccination choices in the population, and *individual and group influences* that include personal perceptions or beliefs about vaccines and influences from the social environment.^{11,22}

"*Sociodemographic information*" section includes questions on gender, age, ethnicity, education, country of birth and occupation.

In "*sources of information*" section, participants were asked to indicate their source of information on AVDs and whether they had ever contracted COVID-19. Finally, "*propensity, attitude and concerns regarding new SARS-CoV-2 vaccine doses*" section includes questions about any previous vaccinations received (flu, mpox, primary COVID-19 cycle), current propensity, attitude and concerns regarding AVDs, and participants were asked to indicate their motivation for adhering or not adhering to AVDs.¹³ The full version of the survey can be found in Supplementary file_1.

Ethical considerations

HIV-VAC Study (version 3.0, 12 September 2022) has been approved by Ethics Committee of 'INMI Lazzaro Spallanzani' (approval number: 91/2022) and all included subjects have signed an informational consent (version 3.0, 12 September 2022) for participation in the study and processing of personal data,

according to Italian legislation. The study was conducted in accordance with the Declaration of Helsinki. Informed consent was obtained from all participants involved.

Statistical analyses

Data are expressed as median and range for continuous variables, based on their distribution, and as counts and percentages for categorical variables. Between September 2022 and June 2023, 316 HIV-positive patients undergoing clinical follow-up were consecutively enrolled. The sample size was considered adequate based on a statistical power calculation (≥ 200 subjects needed to detect 10% differences in vaccination adherence rates, $\alpha = 0.05$; power = 80%). The sample is representative of patients in regular care, but generalizability to PWH who are not in regular contact with health services is limited. Furthermore, the population consisted mainly of males, Caucasians and individuals over the age of 50. These characteristics are in line with the epidemiological profile of PWH in Italy and in high-income European countries, where the epidemic mainly affects men who have sex with men (MSM) and the HIV population is progressively older. Therefore, the sample analyzed can be considered representative of the population with HIV in similar European contexts, while it does not reflect the characteristics of the global population with HIV, in which women and younger individuals constitute a substantial proportion, especially in low- and middle-income countries.

Normality distribution of data was assessed by Wilk-Shapiro tests and where necessary by Quantile-quantile plot (QQ-plots). The normality of the data distributions and homogeneity of variances were evaluated for appropriateness prior to conducting the statistical tests. Depending on the distribution of the data, parametric or non-parametric tests were used. Receiver Operating Characteristic (ROC) analysis was applied to the continuous variable of age to estimate the most appropriate cutoff values and to divide patients into two groups with different outcome probabilities (compliant vs. non-compliant). The age limit was correlated with the outcome variable ($p = .003$). Comparison between treatment groups was performed using the Chi-squared test or Fisher exact test and the Mann-Whitney U test, as appropriate. A multivariable logistic regression model was used to assess the influences of covariates demographic/behavioral on the endpoint.

The following factors were investigated as potential predictors on the endpoint, based on the relevant scientific literature: age, ethnicity, sources of information on vaccination and educational level (independent variables). The dependent variable of the model was the absence of compliance to AVDs. The p -values $< .05$ were considered significant. All analyses were performed using the statistical software SPSS (v. 29.0, SPSS Inc., Chicago, IL, USA).

Results

Respondent characteristics: descriptive results

During recruitment, data on subjects who declined to participate in the study were not systematically collected; therefore, the analysis of the results was based exclusively on participants who completed the survey.

A total of 316 participants were included in the final analysis, the majority (68.4%) were aged 50 years and older, and were Caucasian (91.3%) males (79.7%) with a high school diploma (45.5%), who were employees (20.5%). Most had never tested positive for COVID-19 (58.7%), nor received the flu vaccine (55%). The majority relied on their family doctor for vaccine-related information (38.8%).

The non-compliant group consisted mainly of 50 years old or older (31%) and Caucasians (26.6%) participants. A significant proportion had already had COVID-19 (27.9%) or received previous Monkeypox vaccination (27.5%). In terms of information, non-compliant were more likely to rely on non-institutional sources (46% friends, internet, social media) in contrast to compliant who relied more on vaccination center operators (92.6%). Vaccine non-compliant patients did not differ from vaccine compliant patients by sex, education level, employment or a history of receiving a flu vaccine (Table 1).

Table 1. Sociodemographic, clinical characteristics and survey responses of PWH: comparison between the two outcome groups, compliant vs. non-compliant to additional vaccine doses (AVDs) of the SARS-CoV-2 vaccine, from September 2022 to June 2023 in Rome, Italy.

Variables		N (100%)	Non-compliance N = 76 (24.1%) N (%)	Compliance N = 240 (75.9%) N (%)	P value
Age	≥50	197 (68.4)	61 (31)	136 (70)	.003
	<50	91 (31.6)	13 (14.3)	78 (85.7)	
Gender	Male	252 (79.7)	58 (23)	194 (77)	.322
	Female	62 (19.6)	18 (29)	44 (71)	
	Not binary	2 (0.7)	0 (0)	2 (100)	
Ethnicity	Caucasian	282 (91.3)	75 (26.6)	207 (73.4)	.002
	Other	27 (8.7)	0 (0)	27 (100)	
Education	High school diploma	137 (45.5)	32 (23.4)	105 (76.6)	.506
	Secondary school	69 (22.9)	22 (31.9)	47 (68.1)	
	Degree	50 (16.6)	13 (26)	37 (74)	
	Specialization	25 (8.3)	4 (16)	21 (84)	
	Primary school	20 (6.6)	4 (20)	16 (80)	
Employment	Retired	65 (21.8)	16 (24.6)	49 (75.4)	.944
	Employee	61 (20.5)	16 (26.2)	45 (73.8)	
	Freelancer	40 (13.4)	10 (25)	30 (75)	
	Unemployed	36 (12.1)	10 (27.8)	26 (72.2)	
	Dependent	30 (10.1)	10 (33.3)	20 (66.7)	
	Worker	26 (8.4)	6 (23.1)	20 (76.9)	
	Other	21 (7)	4 (19)	17 (81)	
	Manager	10 (3.4)	2 (20)	8 (80)	
	Student	6 (2)	1 (16.7)	5 (83.3)	
	Merchant	4 (1.3)	0 (0)	4 (100)	
Previous covid19 positivity	No	158 (58.7)	44 (27.8)	114 (72.2)	.989
	Yes	111 (41.3)	31 (27.9)	80 (72.1)	
Previous flu vaccination	No	169 (55)	38 (22.5)	131 (77.5)	.308
	Yes	138 (45)	38 (27.5)	100 (72.5)	
Previous Monkey-pox vaccination	Yes	244 (87.8)	67 (27.5)	177 (72.5)	
	No	34 (12.2)	6 (17.6)	28 (82.4)	.223
Source of information	Family doctor	112 (38.8)	34 (30.4)	78 (69.6)	<.0001
	Vaccination center operators	68 (23.5)	5 (7.4)	63 (92.6)	
	Friends/internet/book/social	50 (17.3)	23 (46.0)	27 (54.0)	
	Other	49 (17)	8 (16.3)	41 (83.7)	
	Institutional website	10 (3.5)	4 (40)	6 (60)	

Reasons for compliance/noncompliance to AVDs

Concerning non-compliance PWH, most of the respondents selected the option “I am concerned that the possible side effects of the new doses of the COVID-19 vaccination may interfere with my health and my usual activities” (31.6%). Consistently, 2.6% selected the option “I am afraid to undergo the new doses of the SARS-CoV-2 vaccines because I have recently had Monkey-pox vaccination.” The most frequently reported combination of reasons was the “fear of toxicity of AVDs” and the “fear of side effects of AVDs.” This combination was observed in 4 participants (6.2%) in the group of the fourth dose and in 1 participant (7.7%) in the group of the fifth dose. Among subjects under the age of 50, the most common combination included “fear of toxicity of AVDs,” “fear of side effects of AVDs” and “recently contracted COVID-19” (n = 1; 7.1% among those non-compliance with the fourth dose; absent among those non-compliance with the fifth dose). Among subjects aged 50 years or older, instead, the most frequent combination for the fourth dose included “fear of side effects of AVDs” associated with “prefer a natural immunity” (n = 3; 6.1%). With regard to the fifth dose, the prevailing combination remained “fear of toxicity of AVDs” and “fear of side effects of AVDs” (n = 1; 7.7%). See [Figure 1](#).

Most of the compliance PWH, instead, selected the option “i think the new vaccine doses will help protect me from infection” (62.5%) as their reason for compliance. Their source of information was either the family doctor or the vaccination center. Only a minority of them, meanwhile, selected the option “the government has released sufficient data on the safety and efficacy of the additional vaccine doses” (0.8%). [Figure 2](#) shows the response percentages for each of the options to the question: “I WILL HAVE IV and/or subsequent doses of anti-SARS-CoV-2 vaccines because.” The most frequently reported combination of motivations was the desire for “protection from infection” within “civil liability.” This combination was observed in the overall sample (n = 5;

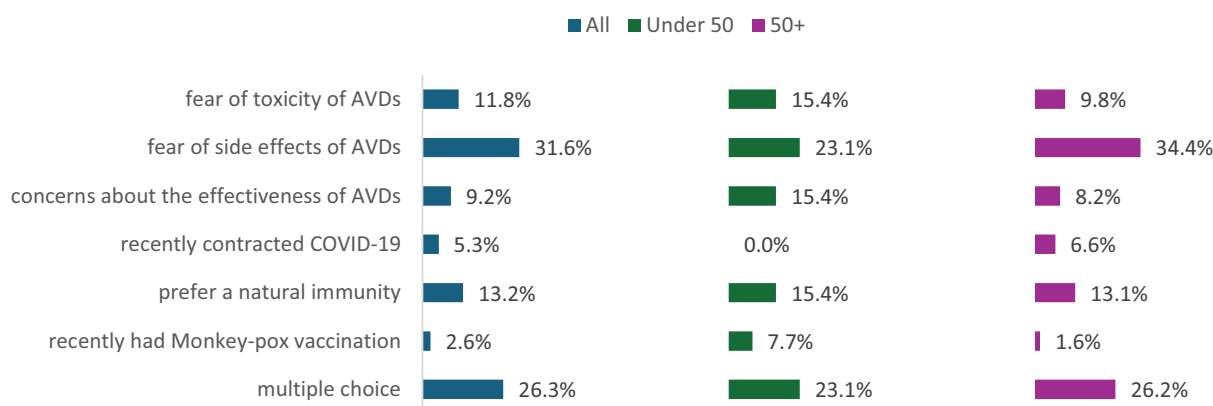


Figure 1. Response rates on non-compliance reasons to additional vaccine doses (AVDs) of the SARS-CoV-2 vaccine among pwh (September 2022–June 2023 in Rome, Italy). “I WILL NOT HAVE IV and/or subsequent doses of anti-SARS-CoV-2 vaccines because”: a. I am concerned about the toxicity of new doses of the COVID-19 vaccination; b. I am concerned that the possible side effects of the new doses of the COVID-19 vaccination may interfere with my health and my usual activities; c. I am concerned about the effectiveness of the new doses of the COVID-19 vaccination; d. I am concerned about the safety of new doses of the COVID-19 vaccination; e. I am concerned about getting vaccinated because I have recently contracted COVID-19; f. I prefer to acquire a natural immunity by contracting the infection; ONLY IF HAVE HAD MONKEY-POX VACCINATION g. I am afraid to undergo the new doses of the SARS-CoV-2 vaccines because I have recently had Monkey-pox vaccination. Most common combination of responses: all “fear of toxicity of AVDs” and “fear of side effects of AVDs” (n = 4, 6.2% 4th dose and n = 1, 7.7% 5th dose); Under 50: “fear of toxicity of AVDs,” “fear of side effects of AVDs,” and “recently contracted COVID-19” (n = 1.7.1% 4th dose, none in 5th dose); 50+ “fear of side effects of AVDs” and “preference for natural immunity” (n = 3, 6.1% 4th dose) and “fear of toxicity of AVDs” and “fear of side effects of AVDs” (n = 1, 7.7% 5th dose).

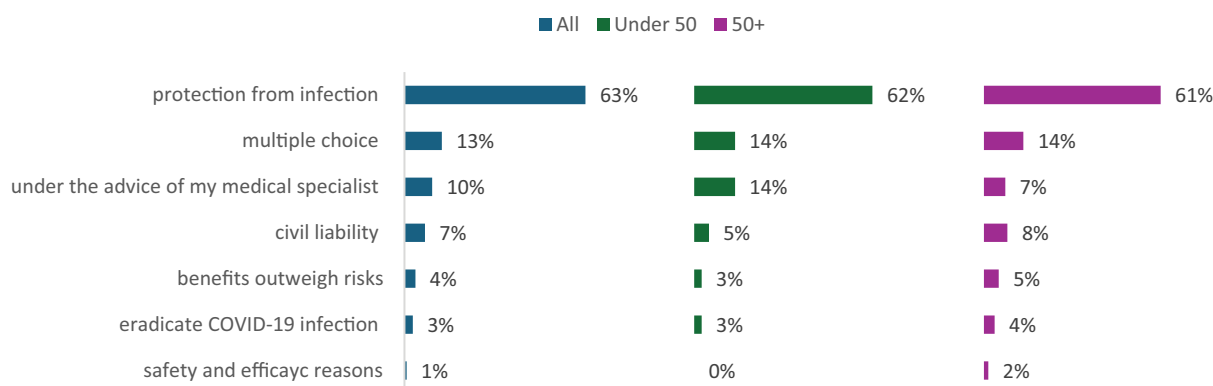


Figure 2. Response rates on compliance reasons to additional vaccine doses (AVDs) of the SARS-CoV-2 vaccine among pwh (September 2022–June 2023 in Rome, Italy). “I WILL HAVE IV and/or subsequent doses of anti-SARS-CoV-2 vaccines because”: a. I think the new vaccine doses will help protect me from infection; b. Under the advice of my general practitioner/specialist; c. I feel that the benefits of undergoing the new vaccine doses outweigh the risks; d. Getting vaccinated against COVID-19 is a civil liability; e. The government has released sufficient data on the safety and efficacy of the new vaccine doses; f. Will help weaken and eradicate COVID-19 infection. Most common combination of responses: all and Under50 “protection from infection” and “civil liability” (n = 5, 21% and n = 2, 2.6%); 50+ “protection from infection” and “under the advice of my medical specialist” (n = 4, 2.9%).

21%) and was also the most common among participants under the age of 50 (n = 2; 2.6%). In subjects aged 50 years or older, the prevailing combination included the “protection from infection” within “under the advice of my medical specialist” (n = 4; 2.9%).

By stratifying by age, the reasons for the compliant group were similar (Figure 2), while in the non-compliant, a small difference was observed in “concerns about the efficacy of AVDs” and “fear of side effects of AVDs” reasons.

These data essentially overlap with those of non-compliers PWH aged 50 or older, mostly worried about potential side effects (34.4%) but often there were multiple reasons given per individual to justify their decision (26.2%). The response rates for noncompliance to the question: “I WILL NOT HAVE IV and/or subsequent doses of anti-SARS-CoV-2 vaccines because” are shown in Figure 1.

Main findings

PWH who were aged >50 years and older were significantly more likely to be non-compliant to AVDs compared to those who were <50 years (OR 2.7, 95% CI 1.2–6.1, $p = .012$). Moreover, those who obtained their information from non-institutional sources such as friends, internet, books, or social media were more likely to be non-compliant when compared with those who obtained information from vaccine center operators and websites of public institutes (OR 0.07, 95% CI 0.0–0.2, $p < .0001$ and OR 0.2, 95% CI .0–0.5, $p = .002$, respectively). Participants sex, previous COVID-19 positivity, having been vaccinated against flu or Mpox, or sourcing vaccine information from a family doctor, had no influence on vaccine compliance (Table 2).

An assessment of the ages of persons who obtained vaccine information from various sources illustrated a homogenous median age across different sources of vaccine information (Supplementary file_Figure 1).

Intentions vs. actual behavior

Regarding PWH non-compliant participants, 95.2% refused to take the fourth dose and 100% the fifth dose, showing a stronger association between intention and behavior ($p < .0001$). They consisted mainly of 50 years old or older (68.4%), male (68%) and Caucasians (70%) participants, with a high school diploma (67.6%), but the majority did not received previous flu (74%) or Monkey-pox vaccination (71.8%). Contrary to what was previously stated in terms of information, most of them were more likely to rely to family doctor (65.4%) and vaccination center operators (71.4%).

In contrast, of the compliant PWH participants, those whose intention to be vaccinated is declared by the interested one, 30.4% have actually received AVDs. The majority (31.6%) were aged 50 years and older, Caucasian (30%) and males (32%) with a high school diploma (32.4%). Most had never had COVID-19 infection (33.8%) and received the flu vaccine (34%). In addition, they relied on their family doctor for vaccine-related information (34.6%). All sample characteristics are described in Supplementary file_Table 2.

Table 2. Results of multivariate analysis predicting of non-compliance to additional vaccine doses (AVDs) of the SARS-CoV-2 vaccine among pwh from September 2022 to June 2023 in Rome, Italy.

Variables	OR (CI95%)	P value
Age (yrs)		
≥50 vs <50	2.768 (1.252–6.116)	.012
Gender		
Female vs Male	2.191 (0.944–5.085)	.068
Education	–	.099
Secondary school vs Primary school	2.010 (0.417–8.843)	.356
High school vs Primary school	0.793 (0.197–3.188)	.744
Degree/specialization vs Primary school	0.597 (0.139–2.567)	.488
Covid19 positivity		
Yes vs No	1.197 (0.617–2.321)	.595
Flu vaccination		
Yes vs No	1.515 (0.779–2.945)	.221
Monkey-pox vaccination		
Yes vs No	1.009 (0.340–2.997)	.988
Information	–	<.0001
Family doctor vs Friends/internet/Book/Social	0.515 (0.229–1.159)	.109
Vaccination center operators vs Friends/internet/Book/Social	0.071 (0.020–0.253)	<.0001
Websites of public instit/other vs Friends/internet/Book/Social	0.218 (0.082–0.580)	.002

OR: Odds Ratio.

CI: Confidence Interval.

Discussion

In this study, we aimed to investigate the attitudes of an Italian sample of PWH toward the SARS-CoV-2 vaccine by analyzing the empirical factors associated with noncompliance and actual behavior toward the administration of additional doses (fourth and fifth doses).

Our data show that minority of PWH did not complied with the vaccination schedule. Among the reasons for noncompliance, concerns about the side effects of AVDs prevailed.

Futhermore, older PWH showed higher noncompliance with AVDs than younger PWH. Being informed through unofficial sources, such as friends, internet, books or social media rather than vaccination center staff and/or institutional public websites, appears to be associated with a significantly higher risk of noncompliance with vaccination.

Finally, non-compliant PWH participants show a strong consistency between intention and actual behavior with regard to vaccination, compared to compliant PWH participants.

COVID-19 vaccination coverage in PWH: strengths and gaps

Can living with HIV be a factor in favor of adherence to COVID-19 vaccination programs? Our evidence shows that in most cases the answer is yes, but there is a minority of PWH who decide not to comply with the COVID-19 vaccination program. Consistent with the findings of a survey conducted in Turin, while 86.2% of PWH participants were vaccinated, 7.6% did not want to be vaccinated.²³ Among the reasons for non-adherence there are mistrust of healthcare systems and operators, lack of information on vaccine risks, and the perception of judgment by medical staff.²⁴ In the Italian ICONA network, less than 10% of PWH had not started COVID-19 vaccination, which had been available since March 2021, by October 2021, while over 85% had completed the entire program.²⁵ More recently, a 2023 meta-analysis reports that effective vaccination coverage among PWH in the European Region reached 90.1%.²⁶

These data are reassuring when we consider that, although some patients remain vulnerable due to incomplete vaccination, overall adherence is high and reinforce the importance of tailored strategies to reach the minority of PWH who do not complete the recommended vaccination schedule. Integrating COVID-19 vaccination into routine HIV care visits, strengthening trust between patients and healthcare providers, and addressing vaccine hesitancy through culturally sensitive communication can help bridge this immunization gap.

AVDs in PWH: protection vs. concerns

Our study also examined the reasons for compliance and noncompliance with AVDs. The most common reason for compliance among PWH was related to the protection against infection offered by AVDs.

This compliance motivation is closely linked to the concept of perceived risk of COVID-19 infection in PWH: the desire to protect oneself against SARS-CoV-2, provided by an adequate understanding of the need for protection achieved with the booster doses, is a significant motivator for compliance with AVDs.^{27,28} Tangible protection, in terms of increased neutralizing antibodies and increased CD4 cells after additional dose, provides real scientific justification for the motivation perceived by PWH: feeling more effectively immunized against COVID-19 infection.

On the contrary, the main reason for noncompliance was concern about the impact of AVDs on daily activities, particularly among PWH aged 50 or older.

Previous studies have shown that uncertainty about side effects and their impact on everyday life is an important determinant of vaccine hesitancy, both in the general population and among PWH.^{23,29–32} However, in our study, we observed an unexpected higher rate of noncompliance to AVDs among older PWH compared to younger ones. The literature tends to report greater hesitancy among younger PWH than among older ones,^{33–35} and in some cases, that age is not always a decisive predictor of vaccine hesitancy among PWH.³⁶ However, in older PWH, concerns about side effects may be amplified by the presence of comorbidities, previous experiences of toxicity related to antiretroviral therapies, and a reduced

social support network, which can make even mild post-vaccination symptoms potentially disruptive.^{27,37–39}

To address concerns about the side effects of AVDs and encourage compliance, healthcare professionals should establish communication based on active and empathetic listening to PWH patients, providing clear and personalized information about side effects, explaining monitoring over time, addressing cases of social isolation by adapting advice to the patient's clinical and social profile, and advising patients to avoid unofficial sources of information on AVDs.

Official vs. unofficial information sources and vaccine adherence

Being informed about AVDs through unofficial sources, such as friends, the internet, books, and/or social media rather than vaccination center staff, public institutional websites, and/or healthcare professionals, seems to be associated with a significantly higher risk of noncompliance with AVDs.

Misinformation about COVID-19, especially on social media, is widespread and might be harmful, creating alarmism based on unscientific theories.

Unofficial information has often been associated with suspicion and uncertainty, increasing the risk of noncompliance with vaccination.⁴⁰ Official information, on the other hand, provided by health professionals or institutional websites, tended to be perceived as more reliable, reducing the risk of noncompliance.^{41,42}

PWH may have to rely on information received from their healthcare providers, which may reduce their likelihood of being hesitant to receive the AVDs.^{13,43}

It is therefore clear how essential it is for vaccine compliance that awareness campaigns focus on official sources, such as healthcare professionals and government agencies, as these are perceived as more reliable than information from social media or friends.

From intention to behavior: AVDs in PWH

Non-compliant PWH participants show a strong association between intention and actual behavior with regard to AVDs, compared to compliant PWH participants.

More in general, noncompliance can be considered a sign of psychological stability in the intention to refuse vaccination, while those who comply may have had more ambivalent or changeable initial intentions, influenced by changing factors such as the information or advice they received.^{44,45} This discrepancy can be interpreted by considering that, as the literature suggests, a positive attitude toward a health intervention does not always translate into behavior, due to factors such as “vaccine fatigue,” low perception of personal risk, the presence of practical and logistical barriers, or selective trust in health institutions.^{46,47} On the other hand, this discrepancy could probably due to a perception of a decrease in the danger of contracting COVID-19 infection over time. It is therefore possible that the stated confidence in additional doses reflects a general attitude favorable to vaccination, without, however, determining concrete adherence to the campaign. Recognizing this distinction is essential. While strategies to promote adherence should continue to focus on transparent and personalized communication – especially for those with uncertain or ambivalent attitudes – it is equally important to acknowledge that individuals with stable anti-vaccine intentions may require different, long-term engagement approaches that go beyond traditional informational campaigns.

Strengths and limitations

The main strengths of the study lie in its methodological approach, which ensured the reliability and validity of the results obtained. In particular, the extended data collection period (six months) was a key element: this time frame allowed for the observation and recording of any fluctuations in vaccination intentions and behaviors linked to external factors (e.g., new pandemic waves, institutional campaigns, changes in vaccine availability). In addition, the study was conducted in a hospital clinic specializing in the management of HIV infection, which is a reference center in Italy given the large number of PWH continuously monitored and the scientific output on the subject. Furthermore, the center regularly

offers COVID-19 vaccination as an integral part of HIV care services. Direct verification of actual vaccine adherence was possible thanks to the continuous comparison of stated intentions and actual behaviors, thanks to the availability of up-to-date clinical data and continuous interaction between patients and healthcare professionals. The study has some limitations. First, the size and likely self-selection bias of our sample, which consisted predominantly of males, Caucasians, and individuals over 50 years of age who voluntarily participated in the study, partly reflects the HIV-infected population in high-income European countries but is not representative of the global HIV-infected population. Therefore, the results should be interpreted with caution and generalized only to similar contexts. Secondly, the lack of data on those who refused to participate in the study is a limitation that led us to discuss the results in terms of compliance rather than hesitancy, considering that the subjects included had already consented to the initial vaccination doses and agreed to complete the survey. Finally, this is a single-center analysis, which could affect the generalizability of the results, therefore further cross-sectional and longitudinal research is needed.

Conclusions

COVID-19 vaccine noncompliance among PWH in Italy is low and non-adherence to AVDs may stem from a deep-rooted and stable belief rather than uncertainty or misinformation. However, perceptions of vulnerability and awareness of the risks associated with HIV-COVID-19 co-infection promote vaccine uptake.

Therefore, healthcare professionals need to be regularly trained to address PWH concerns in an empathetic and personalized manner, particularly those related to the side effects AVDs and should target the most hesitant groups of PWH (e.g., those over 50 years of age), emphasizing the use of official source of information and managing cases of social isolation, improving doctor-patient communication through counseling tools specifically designed for PWH, using standardized information materials that can be adapted to different levels of health literacy, and strengthening the role of health institutions as the primary source of information for the population that lives with HIV.

Finally, conducting multicentre longitudinal studies to assess the evolution of vaccination intentions and behavioral determinants over time and exploring the motivations of non-compliant individuals through qualitative approaches (e.g., interviews, focus groups) are essential aspects of robust future research on vaccine hesitancy among PWH.

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Author contributions

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Data availability statement

The datasets generated and/or analyzed during the current study are not publicly available due to patient privacy reasons, but are available from the corresponding author on reasonable request.

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