PROPOSITION OF PLWH NOT VACCINATED FOR COVID-19 IN ITALY AND PREDICTORS

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BACKGROUND

- The **vulnerability of** people living with HIV (**PLWH**) **to COVID-19** passes through complex mechanisms, intersecting **biological and structural determinants**:
  - A low CD4 cell count and the excess burden of age-associated comorbidities in PLWH seem to led to a greater risk of severe COVID-19 outcomes [1,2]
  - HIV and SARS-CoV-2 share common socio-economic determinants of both their acquisitions and clinical impact [3, 4].
- The COVID-19 vaccination campaign led to a substantial public health benefit, but vaccine hesitancy or issues to vaccine access could undermine the efforts, especially in a vulnerable group as PLWH.

AIMS

We aim to determine the COVID-19 vaccine coverage among PLWH in Italy and to identify predictors of missing vaccination.

METHODS

STUDY DESIGN

Cross sectional study conducted in the Italian Icona Foundation cohort:

- PLWH enrolled in the cohort with at least one clinical follow-up in 2020-2021 and belonging to a subgroup of 18 centers participating to the study, have been included.
- The vaccination status for COVID-19 for all the included PLWH have been evaluated in a 20-day period starting on September 19th till October 8th, 2021, before entering in the 3rd additional dose campaign for fragile populations in Italy.
- Vaccination status has been collected using medical records of each subjects and/or administrative databases if available.

STATISTICAL ANALYSIS:

- Clinical and demographic characteristics have compared using Chi-square and non parametric tests, as appropriate, for vaccinated and not. Clinical characteristics have been evaluated using March 2021 data (as in March 2021 started the COVID-19 vaccination campaign for PLWH in Italy).
- The outcome of interest was the **percentage of PLWH who have not received at least one COVID-19 vaccine dose**.
- Crude and adjusted logistic regression models has been used to identify **predictors of not being vaccinated**.

RESULTS

- 3,704 PLWH has been included in the study. 9/18 centers organized the COVID-19 vaccination campaign for all the PLWH in care, without limitations of CD4 strata, age of comorbidities, inside the center.
- 355/3,704 PLWH resulted to be still not vaccinated (9.6%, 95%CI 8.6-10.6) and 3,349 received **at least one dose** (**90.4%,** 95%CI 89.4-91.3). The **full cycle** has been completed by 3,153 subjects (**85.1%**, 95%CI 83.9-86.2).
- Almost **90%** of HIV population vaccinated received a **mRNA vaccine** (57.9% BNT162b2 and 32.0% mRNA-1273), ChAdOx1 has been used in 4.8% and Ad26.COV2.S only in 1.4% (3.8% unknown vaccine). Characteristics of patients according to being vaccinated with at least 1 dose or not are shown in Table 1.
- In the adjusted logistic regressions, PLWH not vaccinated were more frequently **younger** (per 10 years younger AOR=1.26) and non-Italian native (AOR=1.39), while having a current **HIV-RNA <50 copies/mL** (AOR=0.65), **no previous COVID-19** (AOR=0.48) and being **MSM** (vs. heterosexual AOR=0.68) had lower risk to miss vaccination. Subjects in care for HIV in institutions that set-up a COVID **vaccination center inside** the hospital for all PLWH had a lower risk of not being vaccinated (Table 2).

Table1. Patients' characteristics according to vaccination status

	Not vaccinated		At least 1 dose		p-value	Total	
	n=355	9.6%	n=3349	90.4%		n=3704	100.0%
Sex, Male, n(%)	276	77.7%	2771	82.7%	0.019	3047	82.3%
Age, years, median(IQR)	45	35-53	48	39-57	<0.001	48	39-56
Italian, n(%)	258	72.7%	2803	83.7%	<0.001	3061	82.6%
Year HIV Diagnosis, median(IQR)	2016	2011-2019	2014	2009-2017	<0.001	2014	2009-2017
Mode of HIV Tranmission, n(%)					0.005		
Heterosexual	158	44.5%	1261	37.6%		1419	38.3%
IDU	37	10.4%	254	7.6%		291	7.8%
MSM	145	40.8%	1680	50.2%		1825	49.3%
Other/Unknown	15	4.2%	154	4.6%		169	4.6%
Nadir CD4, cells/mmc, median(IQR)	288	118-429	289	139-423	0.692	289	138-424
Nadir CD4 <200 cells/mmc, n(%)	124	34.9%	1110	33.1%	0.293	1234	33.3%
AIDS, n(%)	47	13.2%	496	14.8%	0.426	543	14.7%
Education, n(%)					<0.001		
Middle School/Elementary	88	24.8%	794	23.7%		882	23.8%
University/High School	122	34.4%	1545	46.1%		1667	45.0%
Unknown	145	40.8%	1010	30.2%		1155	31.2%
Current CD4, cells/mmc, median(IQR)	641	432-841	700	507-931	<0.001	693	501-926
Current CD4<200 cells/mmc, n(%)	26	7.3%	131	3.9%	0.010	157	4.2%
Current HIV-RNA> 50 copies/ml, n(%)	63	17.7%	302	9.0%	<0.001	365	9.8%
Charlson Comorbidity Age-adj median(IQR)	0	0-2	1	0-3	<0.001	1	0-3
At least 1 comorbidity*, n(%)	86	24.2%	1085	32.4%	0.002	1171	31.6%
Previous COVID-19 diagnosis (PCR or Ag)					<0.001		
No	113	31.8%	1398	41.7%		1511	40.8%
Yes	20	5.6%	132	3.9%		152	4.1%
Unknown	222	62.5%	1819	54.3%		2041	55.1%

* Between: Myocardial infarction, Congestive Hearth, Failure Peripheral vascular disease, Cerebrovascular accident, Dementia, COPD, Connective tissue or autoimmune disease, Peptic ulcer, Liver disease (severe or mild), Diabetes mellitus, Hemiplegia, CKD, Solid tumor, Leukemia, Lymphoma, Arterial Hypertension

LIMITATIONS

Selection bias on the population analyzed cannot be ruled out. Personal reasons for COVID-19 vaccine hesitancy in this vulnerable population have not been investigated

CONCLUSIONS

The **acceptance and uptake of vaccine among PLWH has been high**, with a full-vaccination rate higher than targeted general population in Italy in the same period (85.8% vs 78.5% at Week 40-2021[5]). **Barriers** to COVID-19 vaccination access remain for **non-natives Italian** and vaccination hesitancy lasts in **younger** individuals and those with unsuppressed VL. The opportunity of being vaccinated in the individual reference center for HIV care results in higher vaccination rate. Both active recruitment by medical staff and patient's perception of better privacy might explain this finding that together with the other results might be a drive for planning specific **interventions aimed to increase vaccination uptake for PLWH.**

Table2. Odds ratio (OR) and Adjusted odds ratio (AOR) of not being vaccinated for COVID-19

	Unadjusted				Adjsuted Model			
	OR	95%CI		p	AOR*	95%CI		p
Female (vs. Male)	1.37	1.05	1.79	0.020	0.95	0.69	1.31	0.750
Age per 10 years younger	1.29	1.17	1.41	<0.001	1.26	1.12	1.42	<0.001
Not Italian Native	1.93	1.50	2.48	<0.001	1.39	1.04	1.86	0.025
Year HIV Diagnosis, per 1 year less	0.97	0.96	0.99	0.001	1.00	0.98	1.02	0.846
Mode of HIV Tranmission								
Heterosexual	1.00				1.00			
IDU	1.16	0.79	1.70	0.440	1.32	0.85	2.07	0.219
MSM	0.69	0.54	0.87	0.002	0.68	0.51	0.91	0.009
Other/Unknown	0.78	0.45	1.35	0.374	0.71	0.40	1.27	0.249
Nadir CD4 <200 cells/mmc	1.09	0.87	1.38	0.449				
AIDS	0.88	0.64	1.21	0.426				
University/High School (vs Middle School/Elementary)	0.71	0.53	0.95	0.021	0.82	0.60	1.13	0.222
Current CD4<200 cells/mmc	1.95	1.26	3.02	0.003	1.22	0.75	2.00	0.419
Current CD4 per 100 cells/mmc more	0.93	0.90	0.97	<0.001				
Current HIV-RNA < 50 copies/ml	0.45	0.33	0.61	<0.001	0.65	0.46	0.91	0.011
N. Comorbidities								
0	1.00				1.00			
1	0.77	0.58	1.01	0.059	0.96	0.71	1.31	0.807
>1	0.44	0.26	0.72	0.001	0.62	0.35	1.08	0.091
Previous COVID-19 diagnosis (PCR or Ag)								
Yes	1.00				1.00			
No	0.53	0.32	0.89	0.015	0.48	0.28	0.81	0.006
Unknown	0.81	0.49	1.32	0.387	1.00	0.60	1.66	0.989
Vaccination campaign for all PLWH inside the hospital (vs outside)	0.39	0.31	0.49	<0.001	0.34	0.27	0.43	<0.001

Adjusted for all the factors showed in table

BIBLIOGRAPHY

1) Sun J et al. *medRxiv*. 2021. **2)** Dandachi D et al. *Clin Infect Dis*. 2021. **3)** De Ridder D et al. *Front Public Health*. 2021. **4)** Nomah DK et al. *Curr HIV/AIDS Rep*. 2021 **5)** ECDC – COVID19 vaccine tracker

FUNDING

ICONA Foundation is supported by unrestricted grants from Gilead Sciences, Janssen-Cilag, MSD, Thera Technologies and ViiV Healthcare

ACKNOWLEDGEMENTS (ICONA FOUNDATION STUDY GROUP)

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