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Impact of COVID-19 pandemic on retention in care of native and migrant people with HIV in the ICONA cohort☆

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ABSTRACT

Background: COVID-19 pandemic challenged the UNAIDS 90-90-90 targets. How the COVID-19 pandemic affected HIV retention in care and whether it has disproportionally affected migrant people with HIV (PWH) remained to be investigated.

Methods: PWH in ICONA Cohort in follow-up in each of the study periods were included: 01/09/2019-29/02/2020 (pandemic period) and 01/03/2018-31/08/2018 (historical period, as a control). Risk of temporary loss to follow-up (LTFU, defined as no data recorded for a person for one year) was analyzed by logistic regression, with migrant status as the main exposure variable. Difference in difference (DID) analysis was applied to evaluate the effect of COVID-19 pandemic in the different risk of LTFU between natives and migrants.

Results: 8864 (17.1% migrants) and 8071 (16.8% migrants) PWH constituted the pandemic and the historical period population, respectively.

Proportion of PWH defined as LTFU in the pandemic period was 10.5% in native and 19.6% in migrant PWH. After controlling for age, sex and geographical location of enrolling site, risk of temporary LTFU was higher for migrants than native PWH [adjusted odds ratio 1.85 (95%CI 1.54–2.22)] in pandemic period. In PWH contributing to both periods, LTFU was 9.0% (95% CI 8.3–9.8) in natives vs 17.0% (95% CI 14.7–19.4) in migrants during the pandemic. Instead, LTFU was 1.2% (95%CI 0.9, 1.5) in natives vs 2.2% (95% CI 1.3–3.1) in migrants during the historical period, with a resulting DID of 7.0% (95% CI 4.4–9.6).

Conclusions: A greater proportion of LTFU in migrant PWH was observed in both periods, which remained unaltered over time. Interventions to reduce LTFU of migrants are necessary.

1. Background

The COVID-19 pandemic and the resulting lockdown measures demonstrated a negative impact on HIV epidemic goals, mainly related to the disruption in health care services [1–5]. The lockdown was particularly strict in Italy as compared to other countries in Europe and elsewhere, especially during the first wave of the pandemic. At the

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Abbreviations

PWH	people with HIV
LTFU	loss to follow-up
DID	difference in difference
OR	odds ratio
IQR	interquartile range
CI	confidence interval

beginning of COVID-19 pandemic, healthcare clinics reduced their activity or started virtual visits in telemedicine to decrease SARS-CoV-2 transmission. Persons living with chronic diseases, as persons with HIV (PWH), had their non-urgent appointments postponed, while other patients were afraid of contracting SARS-CoV-2 and reduced the activities that may involve contact with other people [6–8].

Disparity in the risk of acquiring COVID-19, in outcomes of SARS-CoV-2 infection, as well as higher COVID-19 vaccine hesitancy, have recently been described in migrants or ethnic minority group, especially in those with high-risk occupations, social exclusion and with issues to access to information regarding prevention [9–11]. Similarly, worse HIV-related outcomes in migrants when compared to native PWH had already been shown by several authors over the years [12–16].

Loss to follow-up (LTFU) is a relevant hindrance toward achieving the 90-90-90 goal proposed by WHO and many factors could play a role in LTFU: unfavorable socio-demographic status, age, gender, ART side effects [17]. Many studies have demonstrated that economic and social issues, such as poverty, lack of social support [17], occupational status [18,19] and educational status [20] are important factors in HIV continuum of care.

However, few single centers observational studies to date documented the short-term impact of COVID-19 pandemic on PWH care in Italy. In a single-centre retrospective study an increase of missed appointments during pandemic was observed, and in another single-centre retrospective study a relevant decrease of PWH in care was reported [21,22]. Nevertheless, another study demonstrated optimal rates of virological suppression during the pandemic period despite the challenges in HIV services caused by the COVID-19 pandemic [23]. Other conflicting results about how COVID-19 pandemic affected rates of loss to follow-up emerged from further studies by different European countries [24,25].

Little is known about the effect of SARS-CoV-2 pandemic on HIV continuum of care in Italy and in particular if the pandemic could hypothetically have exposed disadvantaged groups (e.g. migrants) to an increased risk of loss to follow-up also in a country like Italy where access to care is universal. In fact, in the Italian health system, the HIV care provided to migrants and natives is expected to be identical in term of access to visit, lab tests and antiretroviral therapy (ART).

Thus, aim of this analysis was to estimate the risk of temporary LTFU in native versus migrant PWH, as a result the potential impact of COVID-19 pandemic on the disruption of health service and other social factors that might have modified the chance of attending the clinics in person.

2. Methods

2.1. Study population

We conducted a cohort study including PWH enrolled in ICONA Foundation Study, which is a prospective multi-centre observational cohort of HIV-1-infected individuals. Epidemiological, demographic, clinical and viro-immunological data are collected for all the enrolled participants. A subset of Icona cohort centers performs an automatic upload of all clinical visits and laboratory examinations directly from electronic clinical charts to Icona central database, without manual input of the data. In contrast, for other sites this occurs via manual input of the data directly into electronic CRFs. More details of the ICONA Foundation study have been previously published elsewhere [26].

The ICONA Foundation study has been approved by Institutional Review Boards of all the participating centers. All PWH signed a written consent form to participate in the study and to processing of personal and clinical data, in accordance with the ethical standards of the committee on human experimentation and the Helsinki Declaration (last amendment October 2013). Study population was PWH at least 18 years old enrolled in ICONA Foundation Study, with active follow up in the study defined periods, defined as below. The dataset used for this analysis was locked on the 11 May 2023.

2.2. Study objectives

The primary objective of the study was to estimate the risk of temporary LTFU in natives versus migrants PWH as a result of the impact of COVID-19 pandemic on social factors and health care.

Secondary objective was to describe viro-immunological characteristics of PWH returned to care after being temporary LTFU in the COVID-19 pandemic period.

2.2.1. Definitions

Migrant status was the main exposure of interest and was defined as being born outside of Italy, based on their geographical origin, which was derived from nationality or from country of birth or origin.

Active follow-up was defined as having at least one record of participants' HIV-1 RNA, CD4 cells count determination, any laboratory exams, ART modification, clinical visit or clinical event during a particular period.

Temporary LTFU was defined as the absence in the ICONA database of the record of any information among HIV-1 RNA, CD4 cells count determination, any laboratory exams, ART modification, clinical visit or clinical event for at least one year.

We identified two study periods: a) the pandemic period, ranging from 1st September 2019 to 29th February 2020 and b) an historical period (control group), ranging from 1st March 2018 to 31st August 2018 (Fig. 1).

The period between 1st March and 31st August 2020 was arbitrary considered as a period during which COVID-19 pandemic might have greatly impacted on disruption of health care service and social factors affecting participants' willing to attend the clinic in person. For each of the periods we defined an 'index date' at the last day of the examined period (August 31st, 2018 for the historical period population and February 29th, 2020 for the pandemic period population).

2.3. Statistical analysis

In PWH under active follow-up in the historical and pandemic periods we evaluated the risk of temporary LTFU over 1 year following the index date (i.e. from 31st August 2018 to 31st August 2019 for the historical period population and from 31st August 2020 to 31st August 2021 for the pandemic period population).

Participants may contribute to the pandemic or the historic population or both. The main exposure of interest in the analysis was participants' origins.

Characteristics of native and migrant PWH were compared by means of a $\chi 2$ test for categorical variables or the Wilcoxon rank sum (Mann-Whitney) test for continuous variables. Time-dependent variables were evaluated at index date.

Odds rate (OR) of becoming LTFU using migrant status as the main exposure of interest was explored by logistic regression model, after controlling for several co-factors. We fitted two separate models, the first only including potential confounders such as biological sex (a binary variable indicating female vs male sex), age (fitted as continuous) and geographical location of enrolling site (fitted as a categorical variable) (model 1) and a second model in which we added to these

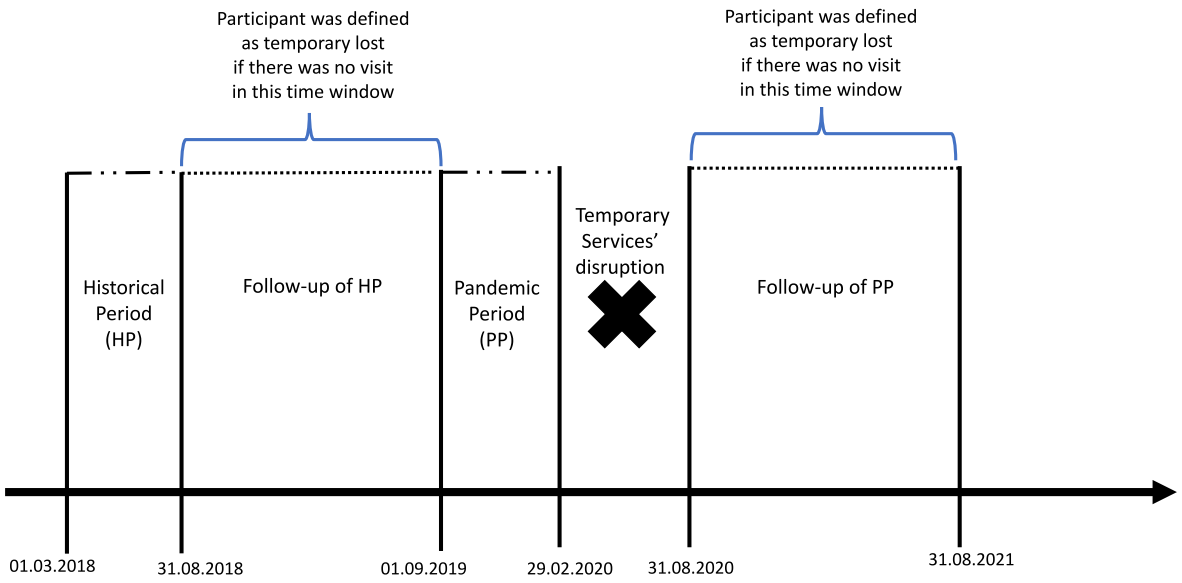

Fig. 1. Description of the study periods.

confounders other important predictors of outcome (some are potential mediators) as AIDS diagnosis (binary variable using the CDC 1993 definition), maximum level of education (categorical variable with 5 levels) and employment (categorical variable with 9 levels) (model 2).

A difference in difference (DID) analysis approach, in participants who contributed to both periods, was used to evaluate the excess of risk of temporary LTFU seen for migrants when compared to natives in the pandemic period compared to the excess risk seen during the control period. Thus this analysis, under our assumptions, aims both to estimate the causal impact of COVID-19 pandemic on the risk of temporary LTFU and to compare the difference in risk by origin before and after the pandemic. In fact, the main limitation when trying to estimate a causal effect from observational data is residual and unmeasured confounding. In this instance, participants in care before and after the pandemic could differ from many factors associated with the risk of discharge from care. A DID analysis restricted to the same population before and after the pandemic is a way of addressing confounding bias. Because participants are the same, if there is a difference in pre vs. post pandemic risk, this can be attributed to the effect of the pandemic itself and not to other factors. Furthermore, a sensitivity analysis restricted to 8 Icona sites with electronic data import for the entire study period, was performed, in order to minimize possible bias due to missing data or delay in data reporting and to get a more accurate estimate for the overall rate of loss to care. In fact, during the Covid-19 pandemic infectious diseases specialists', researchers and data managers were involved on multiple fronts, and manual input of data in eCRF could have experienced missing, reporting delay and quality data could have been affected. In this sense, an analysis that consider only data from prospective automatic upload of clinical and laboratory information directly from electronic clinical charts to Icona central database should provide less biased estimates of the rate of real discharge from care. The HIV care provided is also theoretically consistent across the different Icona participating centers. Participants characteristics, with special focus on predictors of outcome such as level of education and employment, were compared between participants enrolled in centers providing manual vs. electronic data submissions and according to migrant status. A P value < 0.05 was considered as significant. Statistical analysis was conducted using SAS version 9.4 (SAS Institute, Cary NC, USA).

3. Results

3.1. Study population

A total of 8864 PWH constituted the pandemic period population, of whom 1517 (17.1%) were migrants, 1803 (20.3%) were females, median age at index date was 48 years [interquartile range (IQR 39–56)], 1286 (14.3%) with an AIDS-defining event prior to index date, their median $CD4^+$ cells count at nadir was 291 cells/mmc (IQR 147–434), 90.8% with HIV-RNA <50 copies/mL at index date (Table 1). Migrant PWH were more frequently females (38.6% vs 16.6%, $p < 0.001$), had a significantly higher prevalence of prior AIDS diagnosis (17.3% vs 13.7%, $p < 0.001$) and were younger (median age 41 years vs 49, $p < 0.001$) at index date than native PWH. Migrant PWH had also a different geographical distribution in the Italian clinical centers (i.e. they were less represented in Southern regions of Italy), they had significantly lower level of education (9% vs 4%, low education level defined as primary school or below) and were more frequently unemployed than native PWH (20% vs 9%). Migrants were mostly from Central and South America (33.1%) and sub-Saharan Africa (27.6%).

A total of 8071 PWH constituted the historical period population, of whom 1355 (16.8%) were migrants, 1654 (20.5%) were females, median age at index date was 46 years [interquartile range (IQR 38–54)], 1136 (14.1%) with an AIDS-defining event prior to index date, their median $CD4^+$ cells count at nadir was 293 cells/mmc (IQR 151–433), 89.1% with HIV-RNA <50 copies/mL at index date (Supplementary Table 1).

Even in historical period population, migrant PWH maintained analogous differences with native PWH as described above.

The sensitivity analysis restricted to PWH in care at centers for which it was possible to direct import the data electronically included 2357 participants for the historical period population (29% of the total historical period population) and 2630 participants for the pandemic period population (30%). Their main characteristics were similar to those of the overall population described above, except for geographical location of enrolling site, and are presented in Supplementary Tables 2 and 3, respectively. Even in this population, migrant PWH had significantly lower level of education (12% vs 4%, low education level defined as primary school or below) and were more frequently unemployed than native PWH (19% vs 8%). Although migrants were more likely to be unemployed and to have a lower level of education in both the historical and pandemic period, there was no evidence for a difference by center.

Table 1
Main characteristics - pandemic period population.

Characteristics	Migrant PWH	Native PWH	p-value[a]	Total
	N = 1517	N = 7347		N = 8864
Gender, n(%)			<.001	
Female	586 (38.6%)	1217 (16.6%)		1803 (20.3%)
Mode of HIV Transmission, n(%)			<.001	
IDU	45 (3.0%)	737 (10.0%)		782 (8.8%)
Homosexual contacts	529 (34.9%)	3558 (48.4%)		4087 (46.1%)
Heterosexual contacts	858 (56.5%)	2659 (36.2%)		3517 (39.7%)
Other/Unknown	85 (5.6%)	393 (5.3%)		478 (5.4%)
AIDS diagnosis, n(%)			<.001	
Yes	262 (17.3%)	1006 (13.7%)		1268 (14.3%)
HBsAg, n(%)			0.854	
Negative	1354 (89.2%)	6578 (89.5%)		7932 (89.5%)
Positive	27 (1.8%)	117 (1.6%)		144 (1.6%)
Not tested	137 (9.0%)	652 (8.9%)		789 (8.9%)
HCVAb, n(%)			<.001	
Negative	1326 (87.4%)	6027 (82.0%)		7353 (82.9%)
Positive	87 (5.7%)	908 (12.4%)		995 (11.2%)
Not tested	105 (6.9%)	412 (5.6%)		517 (5.8%)
Age, years			<.001	
Median (IQR)	41 (34, 49)	49 (40, 57)		48 (39, 56)
CD4 count, cells/mmc			<.001	
Median (IQR)	612 (414, 847)	710 (513, 937)		694 (494, 923)
≤200 cells/mmc	100 (6.6%)	269 (3.7%)	<.001	369 (4.2%)
CD4 count nadir, cells/mmc			0.046	
Median (IQR)	278 (125, 443)	293 (152, 433)		291 (147, 434)
CD8 count, cells/mmc			0.730	
Median (IQR)	824 (589, 1109)	811 (595, 1090)		813 (595, 1094)
Viral load, log10 copies/mL			<.001	
Median (IQR)	1.28 (0.00, 1.57)	1.28 (0.00, 1.46)		1.28 (0.00, 1.46)
>500,000 copies/mL, n(%)	13 (0.9%)	28 (0.4%)	<.001	41 (0.5%)
>100,000 copies/mL, n(%)	39 (2.6%)	76 (1.0%)	0.013	115 (1.3%)
≤50 copies/mL, n(%)	1275 (84.3%)	6751 (92.1%)	<.001	8026 (90.8%)
Site geographical position, n(%)			0.027	
North	820 (54.0%)	3867 (52.6%)		4687 (52.9%)
Center	595 (39.2%)	2826 (38.5%)		3421 (38.6%)
South	103 (6.8%)	654 (8.9%)		757 (8.5%)
Smoking, n(%)			<.001	
No	866 (57.0%)	3476 (47.3%)		4342 (49.0%)
Yes	398 (26.2%)	2941 (40.0%)		3339 (37.7%)
Unknown	254 (16.7%)	930 (12.7%)		1184 (13.4%)
Time from HIV diagnosis to index date[b], months			<.001	
Median (IQR)	56 (24, 103)	87 (43, 153)		81 (38, 141)
Education, n(%)			<.001	
Primary school	134 (8.8%)	277 (3.8%)		411 (4.6%)
Secondary school	225 (14.8%)	1496 (20.4%)		1721 (19.4%)
College	333 (21.9%)	2407 (32.8%)		2740 (30.9%)
University	143 (9.4%)	955 (13.0%)		1098 (12.4%)
Other/Unknown	683 (45%)	2212 (30.1%)		2895 (32.7%)
Employment, n(%)			<.001	
Unemployed	296 (24.9%)	642 (10.5%)		938 (12.8%)
Employed	498 (41.8%)	3327 (54.5%)		3825 (52.4%)
Self-employed	143 (12.0%)	1195 (19.6%)		1338 (18.3%)
Occasional	87 (7.3%)	122 (2.0%)		209 (2.9%)
Student	48 (4.0%)	247 (4.0%)		295 (4.0%)
Retired	3 (0.3%)	240 (3.9%)		243 (3.3%)
Invalid	1 (0.1%)	16 (0.3%)		17 (0.2%)
Housewife	54 (4.5%)	171 (2.8%)		225 (3.1%)
Other/unknown	388 (25.6%)	1387 (18.9%)		1755 (20%)
Origin				
North Africa	82 (5.4%)	–		–
Sub-Saharan Africa	419 (27.6%)			
Central and South America	502 (33.1%)			
North America	10 (0.7%)			
Asia and Pacific	109 (7.2%)			
Eastern Europe	301 (19.8%)			
Western and Central Europe	94 (6.2%)			

Notes: IDU, injective drug users; IQR, interquartile range.
[a] Chi-square or Mann-Whitney test as appropriate.
[b] Cross sectional analysis at February 28, 2020.

More in general, both in the pandemic and in the historical period, we found no evidence for a difference in gender, migrant status and previous AIDS diagnosis comparing participants enrolled from centers who submitted the data manually or electronically. However, there was evidence for a difference in the distribution of modality of HIV acquisition (more PWID and less infections through heterosexual contacts in the electronic submission's centers) and a slightly higher prevalence of HCV coinfection, a slightly higher CD4 cells count at index date than PWH in participants enrolled in the manual submission's centers. There was no evidence for a difference in the prevalence of low level of education (primary school or lower) and unemployment by type of center.

Participants who contributed to both periods, constituting the population for the DID analysis, were 6684 (migrants accounted for 15.2% of them) and their characteristics are shown in Table 2. Of these, 2087 (31% of the DID population) belong to the subset of sites with electronic data import in place.

3.2. Risk of temporary LTFU

Proportion of PWH defined as LTFU in the pandemic period was 12%: 19.6% of migrant PWH and 10.5% of native PWH in the overall analysis. In the sensitivity analysis, proportion of PWH defined as LTFU in the pandemic period resulted reduced to 5.9%: 9.5% of migrant PWH and 5.2% of native PWH. In the historical period, proportion of LTFU was 5.4% (9.0% of migrants and 4.8% of natives) in the overall analysis and 3.4% (5.4% of migrants and 3.0% of natives) in the sensitivity analysis.

During the pandemic period, we found strong evidence that the risk of temporary LTFU was higher for migrants than for native PWH; in the unadjusted logistic regression model, a difference of 2-fold between the exposure groups was estimated [OR 2.08 (95% confidence interval (CI) 1.79–2.41); $p < 0.001$]. This result was confirmed after adjustment for

Table 2
Main characteristics - participants who contributed to both periods.

Characteristics	Migrant PWH	Native PWH	p-value[a]	Total
	N = 1015	N = 5669		N = 6684
Gender, n(%)			<.001	
Female	394 (38.8%)	978 (17.3%)		1372 (20.5%)
Mode of HIV Transmission, n(%)			<.001	
IDU	31 (3.1%)	598 (10.5%)		629 (9.4%)
Homosexual contacts	356 (35.1%)	2695 (47.5%)		3051 (45.6%)
Heterosexual contacts	577 (56.8%)	2070 (36.5%)		2647 (39.6%)
Other/Unknown	51 (5.0%)	306 (5.4%)		357 (5.3%)
AIDS diagnosis, n(%)			0.005	
Yes	171 (16.8%)	766 (13.5%)		937 (14.0%)
HBsAg, n(%)			0.210	
Negative	918 (90.4%)	5022 (88.6%)		5940 (88.9%)
Positive	14 (1.4%)	103 (1.8%)		117 (1.8%)
Not tested	83 (8.2%)	544 (9.6%)		627 (9.4%)
HCVAb, n(%)			<.001	
Negative	897 (88.4%)	4545 (80.2%)		5442 (81.4%)
Positive	54 (5.3%)	731 (12.9%)		785 (11.7%)
Not tested	64 (6.3%)	393 (6.9%)		457 (6.8%)
Age, years			<.001	
Median (IQR)	40 (33, 48)	48 (40, 56)		47 (38, 55)
CD4 count, cells/mmc			<.001	
Median (IQR)	615 (402, 843)	695 (507, 916)		684 (487, 909)
≤200 cells/mmc	59 (5.8%)	214 (3.8%)	0.003	273 (4.1%)
CD4 count nadir, cells/mmc			0.204	
Median (IQR)	287 (134, 444)	294 (157, 429)		293 (153, 430)
CD8 count, cells/mmc			0.225	
Median (IQR)	843 (616, 1154)	831 (610, 1103)		833 (610, 1110)
Viral load, log10 copies/mL			<.001	
Median (IQR)	1.28 (0.00, 1.57)	0.30 (0.00, 1.57)		0.78 (0.00, 1.57)
>500,000 copies/mL, n(%)	10 (1.0%)	36 (0.6%)	0.092	46 (0.7%)
>100,000 copies/mL, n(%)	26 (2.6%)	101 (1.8%)	0.212	127 (1.9%)
≤50 copies/mL, n(%)	880 (87.0%)	5154 (91.0%)	<.001	6034 (90.4%)
Site geographical position, n(%)			<.001	
North	551 (54.3%)	2996 (52.8%)		3547 (53.1%)
Center	417 (41.1%)	2216 (39.1%)		2633 (39.4%)
South	47 (4.6%)	457 (8.1%)		504 (7.5%)
Smoking, n(%)			<.001	
No	588 (57.9%)	2674 (47.2%)		3262 (48.8%)
Yes	259 (25.5%)	2303 (40.6%)		2562 (38.3%)
Unknown	168 (16.6%)	692 (12.2%)		860 (12.9%)
Time from HIV diagnosis to index date[b], months			<.001	
Median (IQR)	53 (24, 94)	78 (37, 146)		74 (34, 136)
Education, n(%)			<.001	
Primary school	88 (8.7%)	216 (3.8%)		304 (4.5%)
Secondary school	164 (16.2%)	1189 (21.0%)		1353 (20.2%)
College	223 (22.0%)	1881 (33.2%)		2104 (31.5%)
University	109 (10.7%)	736 (13.0%)		845 (12.6%)
Other/Unknown	431 (42.5%)	1647 (29.1%)		2078 (31.1%)
Employment, n(%)			<.001	
Unemployed	188 (23.7%)	477 (10.1%)		665 (12.1%)
Employed	346 (43.6%)	2609 (55.4%)		2955 (53.7%)
Self-employed	99 (12.5%)	898 (19.1%)		997 (18.1%)
Occasional	49 (6.2%)	98 (2.1%)		147 (2.7%)
Student	28 (3.5%)	169 (3.6%)		197 (3.6%)
Retired	3 (0.4%)	192 (4.1%)		195 (3.5%)
Invalid	1 (0.1%)	9 (0.2%)		10 (0.2%)
Housewife	40 (5.0%)	128 (2.7%)		168 (3.1%)
Other/unknown	261 (25.7%)	1089 (19.2%)		1350 (20.2%)

Notes: IDU, injective drug users; IQR, interquartile range.
[a] Chi-square or Mann-Whitney test as appropriate.
[b] Cross-sectional analysis at August 31, 2018.

biological sex, age and geographical location of site [aOR 1.93 (95% CI 1.65–2.26); p < 0.001] and after further adjusting also for AIDS diagnosis, maximum level of education and employment [aOR 1.85 (95% CI 1.54–2.22); p < 0.001] (Table 3).

Even in the sensitivity analysis, a higher risk of temporary LTFU was observed for migrants when compared to native PWH with the following estimates: OR 1.93 (95% CI 1.34–2.80; p < 0.001) in the unadjusted logistic regression model and aOR 1.86 (95% CI 1.26–2.77; p < 0.001) in the first adjusted model, while the difference in risk was largely attenuated and no longer significant when using the second adjustment set [aOR 1.44 (95% CI 0.90–2.31); p = 0.129] (Table 3).

3.3. Difference-in-difference analysis

DID analysis was performed in the subset of 6684 PWH contributing to both periods. In the historical period, the proportion of PWH with temporary LTFU was 1.2% (95% CI 0.9–1.5) in natives vs 2.2% (95% CI 1.3–3.1) in migrants, with a difference of 1.0% (95% CI 0.0–1.9) between the two groups. In the pandemic period, the proportion of PWH with temporary LTFU was 9.0% (95% CI 8.3–9.8) in natives vs. 17.0% (95% CI 14.7–19.4) in migrants, with a difference of 8.0% (95% CI 5.6–10.4). The resulting DID was 7.0% (95% CI 4.4–9.6, p < 0.0001).

However, in the sensitivity analysis, including participants who contributed to both periods and seen at sites with electronic data import (n = 2087), a lower risk of temporary LTFU was detected for both groups, with migrants in pandemic period still showing the highest risk of temporary LTFU (6.6%, 95% CI 3.9–9.4) but with a much smaller DID of 1.0%, not statistically significant (95% CI: 2.2; +4.3, p = 0.538). Full results are shown in Table 4.

3.4. PWH returned to care after being temporary LTFU

A total of 1067 over 8,86 (12%) PWH were temporary LTFU during the pandemic period. Among them, for 225 (21.1% of LTFU) we found records that they had returned to care before the administrative censoring date, with no evidence for a difference by exposure group: 57 (19.2%) of the lost migrants and 168 (21.8%) of the lost natives (p = 0.618). Only a total of 12 PWH (1.1%) were transferred to other centers not included in ICONA cohort or abroad or withdrew the informed consent, again with no evidence for a difference by group: 3 (1%) in the group of migrants and 9 (1.1%) in the group of natives (p = 0.826). Thus, the majority (77.8%) of PWH who we defined as temporary LTFU

Table 3
Risk of temporary LTFU in the pandemic period.

a) overall analysis							
	N events/exposed (n%)	OR of temporary LTFU					
		Unadjusted OR (95% CI)	p-value	Adjusted1[a] OR (95% CI)	p-value	Adjusted2[b] OR (95% CI)	p-value
Natives	770/7347 (10.5%)	1		1		1	
Migrants	297/1517 (19.6%)	2.08 (1.79, 2.41)	<.001	1.93 (1.65, 2.26)	<.001	1.85 (1.54, 2.22)	<.001
b) In participants seen at sites with electronic data import							
	N events/exposed (n%)	OR of temporary LTFU					
		Unadjusted OR (95% CI)	p-value	Adjusted1[a] OR (95% CI)	p-value	Adjusted2[b] OR (95% CI)	p-value
Natives	113/2189 (5.2%)	1		1		1	
Migrants	42/441 (9.5%)	1.93 (1.34, 2.80)	<.001	1.86 (1.26, 2.77)	0.002	1.44 (0.90, 2.31)	0.129

[a] adjusted for gender, age and geographical location of site.
[b] adjusted for gender, age, geographical location of site, AIDS diagnosis, maximum level of education and employment.

Table 4
Difference in Difference (DID) analysis.

a) Overall analysis		
	Proportion with temporary discharge from care and DID analysis	
	Proportion lost (95% CI)	Difference/DID* 95% CI p-value
Historical period		
Native PWH	1.2 (0.9, 1.5)	0
Migrant PWH	2.2 (1.3, 3.1)	1.0 (0.0–1.9)
Post pandemic period		
Native PWH	9.0 (8.3, 9.8)	0
Migrant PWH	17.0 (14.7, 19.4)	8.0 (5.6–10.4)
Pre-Post pandemic period		
DID		7.0 (4.4–9.6)
b) In participants seen at sites with electronic data import		
	Proportion with temporary discharge from care and DID analysis	
	Proportion lost (95% CI)	Difference/DID* 95% CI p-value
Historical period		
Native PWH	0.7 (0.3, 1.1)	0
Migrant PWH	1.6 (0.2, 2.9)	0.9 (−0.5; +2.3)
Post pandemic period		
Native PWH	4.7 (3.7, 5.7)	0
Migrant PWH	6.6 (3.9, 9.4)	1.9 (−1.0; +4.8)
Pre-Post pandemic period		
DID		1.0 (−2.2; +4.3)

remained effectively LTFU at last available observation, on average 20 months after the end of the pandemic period.

Among those who returned to care after being temporary LTFU with available data at the moment of re-entering in care, 14/203 (6.9%) had a CD4 count below 200 cells/mm^3 and 36/200 (18%) had HIV-RNA >50 copies/mL, without statically significant differences between migrants and natives.

4. Discussion

This analysis aimed to explore the risk of temporary LTFU in migrant PWH and compare it to that of native enrolled in the Icona Foundation study cohort before and after the COVID-19 pandemic. Overall, a higher proportion of participants experiencing a temporary LTFU was found in migrants compared to native PWH, both in the historical period and in the pandemic period (2-fold higher risk, which remained stable over time). As hypothesized, the pandemic has exposed disadvantaged groups, as migrants, to a higher risk of LTFU and 17–19.6% of migrants with HIV in Italy experienced a temporary LTFU during the pandemic period. Anyway, through the DID analysis of the subgroup of participants enrolled in Icona sites which are less affected by missing data and/or delay in data reporting, we found little evidence that the difference in risk between migrants and native became even larger in the year post-pandemic. It must be noticed that logistic regression and DID analysis were performed in different populations, with the latter constituted by PWH that did not get lost to follow-up between the two study periods by definition. It is likely that the rate of loss to follow-up was overestimated in the overall analysis, due to missing data or delay in data reporting which was more severe in centers submitting data manually as compared to those submitting electronic data.

The main reason for the dilution in the DID analysis is a drop in the rate of loss to follow-up in migrants in the centers which submit the data electronically, which was disproportionally larger as compared to the drop seen in the natives. We do not believe that differences in the practice that support migrants by center are a likely explanation for these results, as care is expected to be universal regardless of country of birth and ethnicity across centers. Manual data input is normally performed by medical staff who were under stress during the pandemic. This is likely to have led to an over-estimate of the rate of loss of follow-up due to missing data input, but again we expect this to have occurred equally regardless of patients' country of birth or ethnicity. Although, it is not possible to point out a single reason for the observed discrepancy in results with the data that we have, we can speculate that access to care was a potential determinant. Migrants could have experienced a higher barrier to access to care, especially those enrolled in small clinical centers and cities. The lockdown during the pandemic certainly largely affected mobility and to a greater extent in these areas of Italy. These small clinical centers, not situated in large urban areas, are also those who generally do not provide data electronically to the Icona database. In support of this, there was no evidence that the level of education or unemployment was different when comparing migrants enrolled in the electronical vs. manual data submission's centers.

To our knowledge, this is the first study that evaluates the risk of loss in retention in care in PWH in Italy including follow-up before and after the COVID-19 pandemic period. A recent work of the Spanish PISCIS cohort exploring how the COVID-19 pandemic affected rates of loss to follow-up showed greater rates of LTFU in 2020, but no differences by country of birth between 2019 and 2020 were detected. Unfortunately, the period beyond 2020 was not explored [24]. In contrast, another smaller single-center retrospective French study found that patients with loss of follow-up in 2020 were mainly migrants [25].

Migrant status emerged as a clear risk factor for lower retention in care rates in our study as well as in many different contexts [27–29]; multiple other variables ascribable to socio-economic disparities are also potential determinants of lower access and retention to care including mental illness, place of residence, general deprivation, substance use disorder, younger age [30,31].

Moreover, during pandemic period a higher prevalence of temporary LTFU was detected in the overall general population in comparison to historical period, confirming the results of other studies conducted in US [26,32].

Comparison with other studies in term of incidence and prevalence

of LTFU are difficult to make, since many different definitions of LTFU have been used in the literature. In a previous report from the same ICONA Cohort, 35% of PWH met the definition of LTFU, defined as lack of data for a period of one year and a half or longer after the most recent clinical visit [16]. Our decision of defining as temporary LTFU participants for whom no data were recorded for 1 year post the index date was based on the CDC definition which classifies PWH as retained in HIV medical care if they have documentation of $\geq$2 CD4 cell counts or viral load tests performed >3 months apart during one year of evaluation [33]. Retention in care is an essential target for the HIV cascade of care, it is associated with improved survival rates, diminished HIV-related complications and plays an important role in HIV prevention, by reducing HIV transmission [30,34,35]. In our analysis, only 21.1% returned to care by 20 months from the LTFU episode post pandemic period, but they probably remain at higher risk of subsequent LTFU [36]. Moreover, a relevant proportion (88%) of those who returned to care were not on viral suppression, with a rate that is lower than the viral suppression rate in Italy in recent years (93%) [37].

Our analysis has some relevant strengths: the availability of level of education and employment status as a proxy of socio-economic status, the large sample size through the evaluation of the LTFU in all the ICONA network instead of single centers and the use of a sophisticated approach to analysis aiming to estimate the causal effect of the pandemic in the setting of observational data.

Noticeably, our analysis also has some limitations. First, because of the observational nature of the study, we cannot rule out unmeasured or residual confounding (i.e. social deprivation which is not collected in our database). Establishing sources of measured confounding was also somewhat controversial. We adopted the strategy of including two sets of adjusting factors which led to similar results. Indeed, it is possible that the second adjustment provides a biased estimate towards the null of the total effect of origin on risk of LTFU under the assumption that level of education and employments are on the causal pathway between exposure and outcome. These types of bias are potentially mitigated in the DID analysis which compares the risk of temporary LTFU in the same individuals before and after the pandemic. Second, migrant status was defined only according to country of birth. Third, the main analysis is likely to have led to an over-estimation of the overall risk of LTFU and of the difference between groups post-pandemic period. However, we performed a sensitivity analysis after restricting to sites for which missing data and delay in data reporting should be minimized. On the other hand, this sensitivity analysis prevalently includes data from sites located in the North of Italy so it may not provide a fair picture of the situation at national level. In addition, it is possible that some participants were indeed retained in care through unusual modes of communication (e.g. informal interaction with the clinicians) or by having laboratory tests performed elsewhere outside of the Icona sites, thus we cannot rule out that either analysis led to an over-estimation of the risk of LTFU.

5. Conclusion

In conclusion, we documented an increase in the risk of lost to care of PWH. Migrant PWH appears to be a particularly vulnerable group showing concerning sign of inequality in access to health care as compared to the native population which were present before the pandemic and remained unaltered in more recent months. The implementation of strategies to ensure high level of retention in care, use of best practices for risk stratification and management of loss to follow up are warranted in this setting.

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Ethical approval

The ICONA Foundation study has been approved by Institutional Review Boards of all the participating centers. All PWH signed a consent form to participate in the cohort.

CRediT authorship contribution statement

Roberta Gagliardini: Conceptualization, Investigation, Writing – original draft, Writing – review & editing. **Andrea Giacomelli:** Conceptualization, Data curation, Investigation, Writing – original draft, Writing – review & editing. **Giorgio Bozzi:** Conceptualization, Data curation, Writing – original draft. **Antonella D'Arminio Monforte:** Conceptualization, Supervision, Writing – original draft, Writing – review & editing. **Alessandro Tavelli:** Data curation, Formal analysis, Methodology, Project administration, Resources, Writing – original draft. **Valentina Mazzotta:** Investigation. **Elena Bruzzesi:** Investigation. **Adriana Cervo:** Investigation, Data curation, Formal analysis, Methodology, Software, Writing – original draft, Writing – review & editing. **Annalisa Saracino:** Investigation. **Cristina Mussini:** Investigation. **Enrico Girardi:** Investigation. **Andrea Antinori:** Conceptualization, Writing – review & editing.

Declaration of competing interest

The authors declare the following financial interests/personal relationships which may be considered as potential competing interests:

Roberta Gagliardini reports payments to her institution from Gilead Sciences, speakers' honoraria/educational activities for ViiV Healthcare, Merck Sharp and Dohme and Gilead Sciences, advisor for Theratechnologies, Janssen-Cilag and Gilead Sciences.

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Antonella D'arminio Monforte is a consultant or participated in advisory boards sponsored by Gilead Sciences, ViiV Healthcare, Janssen-Cilag, GSK, Merck Sharp & Dohme and received research grants from Gilead Sciences and ViiV Healthcare.

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All other authors report no conflicts of interest.

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Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.tmaid.2024.102691.

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